

PUTTING PATIENTS FIRST: INCREASING ORGAN SUPPLY FOR TRANSPLANTATION

HEARING BEFORE THE SUBCOMMITTEE ON HEALTH AND ENVIRONMENT OF THE COMMITTEE ON COMMERCE HOUSE OF REPRESENTATIVES ONE HUNDRED SIXTH CONGRESS

FIRST SESSION

APRIL 15, 1999

Serial No. 106-14

Printed for the use of the Committee on Commerce



U.S. GOVERNMENT PRINTING OFFICE

56-603CC

WASHINGTON : 1999

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THURSDAY, APRIL 15, 1999

HOUSE OF REPRESENTATIVES,
COMMITTEE ON COMMERCE,
SUBCOMMITTEE ON HEALTH AND ENVIRONMENT,
Washington, DC.

The subcommittee met, pursuant to notice, at 10:07 a.m., in room 2123, Rayburn House Office Building, Hon. Michael Bilirakis (chairman) presiding.

Members present: Representatives Bilirakis, Upton, Greenwood, Burr, Bilbray, Whitfield, Ganske, Coburn, Cubin, Bryant, Brown, Waxman, Pallone, Green, DeGette, and Barrett.

Staff present: Marc Wheat, majority counsel; Patrick Morrissey, majority counsel; Penn Crawford, clerk; and John Ford, minority counsel.

Mr. BILIRAKIS. The hearing will come to order. I am sure we all admire the patience of the children, particularly, but I do not think we ought to make them wait any longer.

I am pleased to convene this hearing on increasing the supply of organs available for transplantation. The subcommittee's review of these issues is timely because, as we know, next week is National Organ and Tissue Donor Awareness Week.

Last year, this subcommittee held a joint hearing with the Senate Labor Committee to review our Nation's system for organ allocation, and more specifically, the changes proposed by the Department of Health and Human Services. Despite strong differences of opinion, all of the witnesses recognize the severe shortage of organs for transplantation. The question before us now, as then, is what the Federal Government can and should do to improve this situation.

This year, 20,000 people will receive organ transplants, but 40,000 will not. In the last decade alone, the waiting list for transplants grew by over 300 percent. Much of this increase is due to improvements in medical treatments for transplant patients. However, the gap between organ supply and demand remains enormous.

As we consider these issues, we should remember that many successful programs to encourage organ donation have been developed at the State level. In my home State of Florida, the organ procurement program operated by LifeLink has increased donations by 46 percent in the past 3 years alone. Today, John Campbell will describe the innovative strategies LifeLink has employed to increase organ supplies in Florida and Georgia.

This is literally a matter of life and death for tens of thousands of Americans each year. Given the enormity of these issues, we have an obligation to work together to address these concerns on a bipartisan basis. However, the solution to this problem, I am sure we all agree, is not entirely legislative.

By working to increase public awareness about the need for organ donations, we can all save lives. My wife and I were proud to sign the First Family Pledge, which encourages families to talk about the importance of organ and tissue donation, and are hopeful that most of the Congress, if not all of it, will follow suit. Many already have, obviously.

Our first witnesses today are young people who participated in the First Family Pledge Congress, which was held yesterday. Their lives were saved by an organ transplant and they will provide a firsthand perspective on these issues. Their stories should motivate us to redouble our efforts to increase organ donations.

Our second panel of experts will focus on methods being used to increase organ donation and expand organ supply. They will also discuss the reasons why demand greatly exceeds supply in certain areas of the country.

I again want to welcome all of our witnesses and especially our young heroes. I appreciate their time and effort in joining us, and I look forward to hearing their testimony. I will allow the panel to make their opening statements at this time, but I would hope that they could be curtailed in the interest of not extending the patience of the young people on the first panel.

Mr. Brown is recognized for an opening statement.

Mr. BROWN. Thank you, Mr. Chairman. I welcome all of our witnesses. Thank you for coming today and being with us.

I would like to take this opportunity to commend my colleague, Mr. Stark, for introducing the Gift of Life Congressional Medal Act, legislation that recognizes the compassion, humanitarianism, and courage of organ donor families. I am proud to be a cosponsor of this bill.

I am particularly pleased, Mr. Chairman, to welcome our first panel. I understand that Abbey, and it says in front of her name Ms. Johnston, is from Napoleon, Ohio. I live in Lorain, not very far from you, about 100 miles away from you. Welcome to you and to your three friends on the panel. Thank you for coming.

The four of you coming to talk to us today is a better advertisement for organ donation than any billboard or television commercial or long-winded speech that could ever be. Meeting you and hearing your stories makes the need for increased organ donation more real for all of us.

I looked at my own district to get a better sense of the donation shortfall. At any given time last year, more than 1,100 people in Northeast Ohio were waiting for a transplant. Over the same period, there were only 86 organ donors and 231 tissue donors. That is a tremendous gap. Fortunately, there are actions we can take to reduce this critical shortfall.

The U.S. population is increasing but the number of organ donors, unfortunately, is not. As a matter of fact, there has not been a significant increase in the number of organ donors since 1986. At the same time, the number of patients waiting for donated organs

has grown dramatically, driven in part by medical advances and changes in the Nation's demographics.

Research shows we can improve this situation by focusing on two key areas, becoming more diligent in identifying and referring potential organ donors and learning better ways to help families negotiate the difficult emotions around organ donation. Experts believe more than a quarter of medically suitable organ donors go unrecognized. Based on this figure, each year, we forsake thousands—thousands—of critical opportunities to help patients.

But this is not the most common reason that medically suitable organs are not recovered. Family refusal to provide consent for donation is. These families face an untenable decision at a crisis point in their lives. But researchers believe we can encourage more families to consider organ donation by adopting outreach and support models that have met with particular success. According to these researchers, there are fertile opportunities to identify and apply best practices to organ donation, and by doing so we can increase organ donation rates. It will not be easy, but together, we can do it.

Organ donation is such an amazing act of giving, one that delivers hope, health, and time to thousands of patients each year. I look forward to learning more about this issue from our four panelists. Thank you for joining us again.

Mr. BILIRAKIS. I thank the gentleman.

Mr. Bryant, for an opening statement.

Mr. BRYANT. Thank you, Mr. Chairman. I am happy to be here today to learn more about organ donation and transplantation. With all the recent discussions in the medical and health policy communities about how best to allocate the number of donated organs, I am glad that we are choosing to focus today's hearing on the root problem, the shortage of organs available for transplant. Finding ways to increase organ supply is really the best, most direct way to help thousands of patients currently waiting for a transplant and those who will need organs in the future.

I would like to take this opportunity to welcome this most distinguished panel of witnesses. I appreciate each of you taking your time to be here today. I want to particularly welcome Mr. Burton, who is a good volunteer from the State of Tennessee. He lives just outside my district, up around Nashville, but I thank him for being here and I know that you will help us better understand the nature of the problem and how we in Congress can assist you in your efforts.

As a result of you being here and testifying today, all of you, I am going to look at supporting the pledge you have asked us to support regarding organ donations and discussing those, and I will make that commitment to you today, especially for my good volunteer, Mr. Burton.

Thank you, Mr. Chairman and Mr. Brown, for holding these hearings and I yield back.

Mr. BILIRAKIS. Thank you, sir.

Mr. Pallone, for an opening statement.

Mr. PALLONE. Thank you, Mr. Chairman. Let me say that I do think this is a very important hearing and I want to thank you and Mr. Brown for holding it this morning.

Increasing the supply of organs for transplantation is a critical public policy issue in this Nation and an acute problem in my own State of New Jersey and I am grateful for the opportunity to hear from today's witnesses, particularly the first panel here. They look about the age of some of my children.

I want to articulate some of the concerns I have with the impact the current system is having on the ability of organ procurement organizations to focus all of their energies on their mission. New Jersey has one of the finest organ procurement systems in the country and New Jersey's largest organ procurement organization, the New Jersey Organ and Tissue Sharing Network, does an excellent job in organ donation education and in meeting the needs of New Jersey's transplant centers.

One particularly noteworthy aspect of the New Jersey Organ and Tissue Sharing Network's efforts is its work in assisting minority and indigent care communities. New Jersey's network has been recognized nationally for its work in these areas.

My State was also one of the first to pass routine referral legislation and help set the standard that the Federal Government eventually followed, and I am very pleased to note that since the enactment of that legislation, New Jersey has seen a 20 percent increase in donation. Despite this increase, however, there are still flaws in the system that are obstructing the effort to increase organ donation. Like every OPO in the Nation, New Jersey's sharing network must meet HCFA recertification standards every 2 years or face termination.

Mr. Chairman, I wanted to say I am extremely concerned about the unpredictability of the recertification process and the impact it has on the ability of OPOs to focus their energy on increasing organ donations. OPOs must conform to performance thresholds that may have no direct correlation to the OPO service population characteristics and, therefore, no real connection to the actual performance of the OPO.

The recertification process, moreover, allows no time for OPOs to respond to HCFA's findings. Sometimes they are notified only a month or 2 before the recertification deadline, by which time it is too late to address identified problems. HCFA's regulations allow no corrective action plan for the OPOs to improve donation services. In other words, either you meet the arbitrary requirements or you fail. There is no second chance.

Organ procurement organizations are on the front lines of public education efforts and the existence of a performance review process that removes established organizations without due process, or at least an attempt to deal with local demographic realities, is of great concern to me. Organ procurement organizations cannot concentrate fully on programs to increase the supply of organs when they are burdened by the mandate to meet unpredictable national average performance standards over a 2-year period, and such a short cycle simply does not help OPOs implement the best practices to increase the organ supply.

This system is clearly not good for areas with diverse populations and areas with high cancer, HIV, and HVC rates that adversely impact the supply of organs, and accordingly, I would like to see HCFA suspend the certification process so new and better data

from hospital death records and other sources can be studied. Study of new information will allow for a certification process that better reflects actual organ donation potential to be implemented.

My State and other areas with diverse populations and high incidences of disease cannot tolerate the biannual threats to their existence. The system obstructs the access my constituents have to organ donation and transplantation services and this flaw must be addressed, and I am hopeful that today's hearing will move us closer to this goal. Thank you again.

Mr. BILIRAKIS. I thank the gentleman.

Mr. Greenwood, for an opening statement.

Mr. GREENWOOD. Thank you, Mr. Chairman, and thank you for holding this hearing. I think our patients are well named because they are very patient while these Congressmen drone on here.

Over the last 10 years, the number of transplants performed in the country increased by about 56 percent while the number of patients on the waiting list grew by about 316 percent. Some people estimate that less than one-third of the potential donors in America actually contribute. But according to some researchers, it may be possible to increase by 80 percent the number of organ donations in the United States through incentive programs and public education.

In my State of Pennsylvania, we have passed what we call routine notification requirements, that all deaths or imminent deaths be reported to the local OPO. After we did that, within 3 years of doing that, organ donations were up 43 percent in Pennsylvania.

In addition, Pennsylvania offers a \$300 contribution toward funeral expenses to families of organ donors as part of a 3-year pilot program. The money is given directly to the funeral home. Because the program does not give money directly to the donor, it is not considered a direct financial incentive, which is banned under Federal law. The whole question of financial incentives as a methodology of increasing organ donor supply is controversial and raises a variety of ethical questions.

In the audience is a friend of mine and a constituent. His name is Gene Epstein. He has been promoting an idea in which the Federal Government would issue a \$10,000 life insurance policy with benefits payable upon donation and transplantation of the deceased's organs. Mr. Epstein has been working with Dr. Alan Bozeman, a liver transplant recipient, to develop public support for this idea. Dr. Bozeman and Mr. Epstein estimate that if all potential organs were transplanted successfully, the only remaining patients waiting for an organ would be new listees.

This is an intriguing idea. We would have to look at how it would be financed, and I welcome his insights and ask my colleagues to examine his ideas. I also ask unanimous consent that his proposal, entitled "Project Donor," be inserted into the record.

Mr. BILIRAKIS. Without objection.

[The Proposal appears at pg. 87.]

Mr. GREENWOOD. Mr. Epstein has also brought with him a check for \$100,000 payable to the United States Treasury in a gesture to kick-start such a program if the U.S. Congress thought we ought to put it into law. I look forward to today's discussion. Thank you, Mr. Chairman.

Mr. BILIRAKIS. That is some kind of motivation for it.

I might add that in the many discussions that we have had regarding the proper method of organ allocation, Mr. Greenwood constantly reminded us that as important as that was, organ supply or having proper organ supply was just as significant. So this hearing is really somewhat of a testimonial, if you will, to Mr. Greenwood, I would say, more than anything else.

Mr. Barrett, for an opening statement.

Mr. BARRETT. Thank you, Mr. Chairman. Good morning, girls and boys. It is a pleasure to have you here. As adults, we will spend a lot of time talking about how organs should be distributed and what we can do to increase the supply, but in case we are going to have to give you a recess before we actually get to hear your testimony, I just want to thank you for being here and I very much look forward to hearing what you have to say. Thank you, Mr. Chairman.

Mr. BILIRAKIS. Thank you so much.

Mr. Whitfield, for an opening statement.

Mr. WHITFIELD. Mr. Chairman, thank you very much. Like the others on this panel, it is seldom that we have such a distinguished group of young witnesses and I know all of us are looking forward to hearing their testimony because they have the firsthand experience of what transplants are really all about, so I look forward to their testimony and thank you for holding this hearing.

Mr. BILIRAKIS. Thank you. I appreciate that. These young people have been sitting here for quite some time. They are very, very patient, much more so than any of us could be, and so I have asked for brevity in the opening statements.

Mr. Waxman? I do not necessarily intend that to reflect on you.

Mr. WAXMAN. No, I understand. I thank you very much, Mr. Chairman, and I thank the young people for their patience. This is an important hearing and I am glad you have called it. I am really pleased that we have these witnesses here today to talk to us.

It is obvious that unless people have organs for transplantation, some people are unfortunately going to die, which means that we have got to have more organs. I am pleased that the Clinton administration has started a new initiative to get people to be aware of these facts so if an occasion arises, they will either donate their own organs or respond to the call from members of their family, if they suffer a sudden death.

But there is another point. I have been excited at the possibility of stem cell research at UCLA and other places where there is talk that they can develop organs that can be used for transplantation. I would just want to emphasize that we should not do anything to stop this kind of research. We should not let politics get in the way of this research because it holds an enormous amount of promise for the future.

Mr. Chairman, I thank you for this chance to say a few words and to welcome our witnesses today and I want to tell you how much I think it is important that we are holding this hearing and I thank you for it.

Mr. BILIRAKIS. Thank you, sir.

Dr. Ganske, for an opening statement.

Mr. GANSKE. Thanks, Mr. Chairman. I will be brief. I was just thinking that back in 1976, 1977, 1978, I worked with a lot of children who had biliary atresia and would have benefited from transplantation surgery. As I am looking at our first panel here, I was just thinking about the advances that have been made in transplant surgery and we should try to do everything we can to make those benefits available to as many people as possible, and I yield back.

Mr. BILIRAKIS. Thank you, Doctor.

Mr. Green?

Mr. GREEN. Thank you, Mr. Chairman. I will put my full statement in the record, but I want to, like my colleagues, thank Jamar, Abbey Lynn, Cynthia, and Kara Grace and say that I was at the press conference yesterday over on the Senate side and saw some constituents there and I am proud to have made the pledge.

The problem, like my colleague from Pennsylvania said, we have 66,000 people on waiting lists and 20,000 transplants available, so we have to do better to develop the transplants. Coming from Texas, we have a State program that has implemented a number of things to try and increase, and it has worked, and I encourage us to look at that, Mr. Chairman.

[The prepared statement of Hon. Gene Green follows:]

PREPARED STATEMENT OF HON. GENE GREEN, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF TEXAS

Last year the administration made a good faith effort to reduce waiting times for patients who need an organ transplant. Unfortunately, what their plan did not recognize is that merely re-allocating organs under today's levels of supply and demand would save few lives.

The reality is, when you have 66,000 people on waiting lists and only approximately 20,000 transplants, our federal resources would be better spent supporting programs to increase donation rather than to force changes to existing allocation policies.

If we are serious about making a difference, we have to be serious about increasing the number of organ donors.

In most cases, finding the solution to a problem is the hardest part. But in this instance, we know what we need to do, we just don't know the best way to do it.

Fortunately, many states around the country, including my home state of Texas, are starting to figure it out.

For example, within the past few years, Texas has implemented a series of programs to help increase organ donation. These include: 1) Increasing community participation in increasing donor awareness; 2) increasing family consent for donation; and 3) increasing hospital referrals of potential organ donors to the OPO.

While these programs may seem obvious, they resulted in a 12% increase in Texas organ donation last year alone.

Other states have similar programs and have also had excellent results. Now we must join the states and the administration in support of existing programs and do everything possible to encourage other states to initiate new programs.

I look forward to hearing from our witnesses to learn more about what other states are doing, so we can see what is working.

Thank you Mr. Chairman.

Mr. BILIRAKIS. I thank the gentleman.

Dr. Coburn, do you have an opening statement?

Mr. COBURN. Thank you, Mr. Chairman. I am extremely interested in this issue. I have had three of my own pediatric patients transplanted in Oklahoma and three transplanted outside of Oklahoma. I understand the organ availability issue. Oklahoma has worked hard to improve that and increase it, and we have. I think our goal ought to be to find out what we can find during these

hearings and then we ought to make sure that we implement any policy that will increase the available number of organs, regardless of where they are transplanted, and I just want to thank everybody's effort in bringing this issue to the forefront and you for having this hearing. I yield back.

Mr. BILIRAKIS. Thank you, sir.

Ms. DeGette?

Ms. DEGETTE. Thank you, Mr. Chairman. I, too, would like to thank these guys for coming today. It is nice to see all of you here to testify and to tell us about organ transplants.

Just to add a slightly different perspective, I spent some time during the recess up at the Joslin Diabetes Center at Harvard University learning about efforts to improve patient tolerance of transplanted organs. In addition to the many, many people who are on waiting lists right now for organ donations, as Congressman Waxman said, there is enormous potential in years to come for islet cell transplantation.

We have 16 million people in the United States right now who have diabetes. Many of those people, if we could perfect organ transplantation, and tolerance to these transplants, would benefit from pancreatic transplantation and also islet cell transplantation. It could literally cure their diabetes. But in order to do that, we have to improve our transplantation program in this country because we do not even have enough pancreases or other organs for people who are currently on waiting lists.

So I appreciate you holding this hearing, Mr. Chairman, and I yield back the balance of my time.

Mr. BILIRAKIS. Thank you.

Mr. Upton?

Mr. UPTON. Thank you, Mr. Chairman. If there is not a better reason to reauthorize this law, it is the four wonderful kids that are sitting at that table. I have signed the donor pledge. I look forward to working with you to get the job done, and we appreciate the patience of our witnesses. And with that, I will cut short my statement. Thank you.

Mr. BILIRAKIS. I thank the gentleman.

[Additional statements submitted for the record follow:]

PREPARED STATEMENT OF HON. BARBARA CUBIN, A REPRESENTATIVE IN CONGRESS
FROM THE STATE OF WYOMING

Thank you, Mr. Chairman, for holding this important hearing on how to best increase the organ supply for those patients in need of transplantation.

Almost one year ago I, along with other Members of Congress who represent the Northwestern part of the U.S., wrote a strongly worded letter to Secretary of Health Shalala asking that she reconsider the controversial proposed rule on a new organ allocation policy.

In part, the letter pointed out that the "sickest-patient-first" standard, applied on a national basis, would result in more deaths and fewer successful transplants.

In our mostly rural states, where most of the population is spread over large areas and many people live in rural communities, the number of transplants would drop, decreasing access to care if the "sickest-patient-first" standard were applied.

A national list would give transplant programs in high-population-density areas access to more organs. Regions with smaller populations would have fewer. The Northwestern region's success in supplying quality, cost-effective transplants to all regions of the country could be reversed under this standard.

We pointed out that the Organ Procurement and Transplantation Network (OPTN), a consensus based organization of transplant professionals, transplant re-

ipients, organ donors and family members, rejected the "sickest-first" standard because it would not work to ensure the greatest benefit from available organs.

Although I disagreed with much of Secretary's work in this regard, I was very pleased to see that the Department of Health and Human Services has made it a priority for hospitals that participate in the Medicaid and Medicare Programs to implement "routine notification" policies as they relate to organ donations, transplantations, and allocations.

It really is an important step in allowing for better communications among the providers, hospitals and organ procurement organizations (OPOs).

There are many factors that affect the donation of organs, many of which the federal government would have no control over. However, if there is a role that the federal government can play to ensure that those who need an organ transplant receive one in a speedy and dependable manner we need to do that immediately.

I look forward to hearing from the witnesses today to see what their suggestions are in this regard.

Thank you, Mr. Chairman. I yield back the balance of my time.

PREPARED STATEMENT OF HON. TOM BLILEY, CHAIRMAN, COMMITTEE ON COMMERCE

Thank you, Chairman Bilirakis for holding this hearing today on a topic that is literally vital: finding lifesaving solutions to the problem of a short supply of organs available for transplants for Americans in need.

Our first panel of witnesses are all experts in the field of pediatric transplantation. Each of these experts is between the ages of seven and ten years old, and each of them has had at least one organ transplant. Their young and precious lives illustrate why we should do our very best to increase the supply of organs for transplant. Their testimony this morning should remind us in the months ahead, as we consider the reauthorization of the National Organ Transplant Act, that the closure of regional transplant centers cannot occur.

Our second panel of witnesses, or what we will refer to today as the "grown-ups' table," represents those who have dedicated their lives and imaginations to saving the lives of thousands of people each year. It is this panel, in regional transplant centers and organ procurement organizations where innovation and enterprise of the highest order is being carried out.

We will learn of breakthrough treatments from Dr. Marcos at the Medical College of Virginia, where living donors actually donate part of their livers to help someone in need, most often a child. The Medical College of Virginia has had great success in this area, employing exciting procedures where the liver tissue regenerates in both donor and recipient. This procedure promises to free up more donated livers for others, thus easing the pressure on those facing long and life-endangering illnesses. The Medical College of Virginia has performed 25 living donations since the beginning of 1998, and performs more adult-to-adult procedures than any center in the country. Every week, MCV performs about four adult-to-child living donor transplants a week, helping guarantee more birthday parties and summer-time ice cream socials for these children and their families.

Other witnesses we will hear from today will describe ideas put into action by centers which are increasing donation rates and extending supplies throughout the Nation. I ask my colleagues to work with me through the authorization process to encourage the Organ Procurement and Transplantation Network that is increasing the supply of organs, rather than pursue an experimental redistribution program that would result in the closure of regional transplant centers.

Thank you, again, Chairman Bilirakis for calling this hearing, and I look forward to the testimony of our witnesses.

Mr. BILIRAKIS. Our first panel is, of course, the very significant panel of true heroes. Ms. Emily Joan Mahon from the State of Wisconsin was to be a part of the panel, but I understood she took ill this morning and is not able to appear. But we do have Mr. Jamar Burton from the State of Tennessee, Ms. Cynthia Guillemin from my State of Florida, Ms. Kara Grace Thio from the State of North Carolina, and Ms. Abbey Lynn Johnston from the State of Ohio.

Kids, I know you all have a written opening statement that is a part of the record. You are welcome to read that or just speak on your own. Just tell us basically about your experience, whatever

you think is going to be very helpful to us as we confront this problem.

Jamar, why do we not start off with you.

STATEMENTS OF JAMAR BURTON, ORGAN TRANSPLANT RECIPIENT, STATE OF TENNESSEE; CYNTHIA GUILLEMIN, ORGAN TRANSPLANT RECIPIENT, STATE OF FLORIDA; KARA GRACE THIO, ORGAN TRANSPLANT RECIPIENT, STATE OF NORTH CAROLINA; AND ABBEY LYNN JOHNSTON, ORGAN TRANSPLANT RECIPIENT, STATE OF OHIO

Mr. BURTON. I am Jamar Burton from Antioch, Tennessee. I am 10 years old and I am a kidney transplant recipient. I would like to thank the members of this committee for giving me the opportunity to speak about the importance of organ donation.

I have two donors to thank for the miracle that lets me sit here today. The first is my mother, who donated one of her kidneys to me when I was a baby. Unfortunately, a bad case of chicken pox when I was just starting school damaged that kidney, so I needed a second transplant. I was blessed. I got a second kidney in 1995, and now I am doing fine.

But many people are not so blessed. Today, more than 700 people from my State, Tennessee, are waiting for organs. All of them and all of their families are hoping an organ will be available in time, but some of them will be disappointed.

These people do not make the decision to get a transplant by themselves. I know from my own experience, they make the decision with their families. It is a matter that affects the entire family. So why should people make the decision to be an organ donor by themselves? People should discuss organ donation with their family, too.

That is why I think the First Family Pledge idea, getting families to all agree to be organ donors, is the best hope for the thousands of people waiting. I would like to thank all of the Members of Congress, particularly Senator Frist and Congressmen Tanner and Ford, for supporting the First Family Pledge. Thank you.

Mr. BILIRAKIS. Thank you so much, Jamar.
Cynthia, you are up.

STATEMENT OF CYNTHIA GUILLEMIN

Ms. GUILLEMIN. I am Cynthia Guillemin from Miami, Florida. My doctor calls me Madeline, like in the story book, because I lived in France when I was really little. I am 7 years old and my mommy gave me her kidney when I was 6. I would like to thank all you important people for letting me speak to you today.

Just 1 year ago, I was on a kidney machine for a long, long time because my kidneys did not work. My mommy was really nice, kind, to give me one of hers. Many kids like me cannot get this present because their mommies and daddies cannot give it to them. I was very lucky. Many people need to get this gift of life from other families.

Today, more than 1,000 mommies and daddies in Florida who cannot give such presents are waiting for their kids to maybe get them from other families. I say families because when a kid like me, or a mommy or a daddy or a brother or a sister, needs a trans-

plant, they do not wait by themselves. Their whole family hopes and prays for them.

When this present is given, the whole family is happy. The miracle is a family miracle, so we should thank the families who made it happen. If families talk about both parts of this miracle, the giving and receiving of transplants, then everybody will know it is the right thing to do.

That is why I thank you for the First Family Pledge. I would like to thank everybody here, especially Mr. Bilirakis, for signing the First Family Pledge. Thank you. And thank you also to my favorite Dr. Miller who operated me.

Mr. BILIRAKIS. She did considerably better with my name than I did with hers, did she not? Thank you, Cynthia.

Kara Grace?

STATEMENT OF KARA GRACE THIO

Ms. THIO. I am Kara Grace Thio from Cary, North Carolina. I am 7 years old. I am a liver transplant recipient. I would like to thank this committee for letting me speak today.

I received the gift of life when I was 8 months old. Since then, my mother and I are doing all we can to encourage organ and tissue donation.

More than 2,000 people from North Carolina are waiting for an organ to be available. Some will be lucky and get a new chance, like me. Some will be disappointed. I think all of them should have the chance for a transplant.

Yesterday, 200 children like me came to Washington to show Congress how transplants changed our lives. Lots of family members came, too, because transplants change the lives of entire families.

Families should discuss the miracle of transplants. If a member of my family needed a transplant, we all would hope they would get an organ. So should not families all also agree to be organ donors?

It is also important for family members to know about each other's desires to be organ donors because it is the family members who are the ones who make sure that their loved one's wish to be an organ donor gets fulfilled.

That is why we support the First Family Pledge idea. I would like to thank the Members of Congress, particularly Congressman Burr, who is on the Commerce Committee, Senators Helms and Edwards, and Congress members Myrick, Clayton, Watt, Pomeroy, Price, and Jones for supporting the First Family Pledge. Thank you.

Mr. BILIRAKIS. Last, but far from least, Abbey Lynn.

STATEMENT OF ABBEY LYNN JOHNSTON

Ms. JOHNSTON. I am Abbey Lynn Johnston from Napoleon, Ohio. I am 10 years old and I am a liver transplant recipient. I would like to thank the members of this committee for giving me the opportunity to speak today about the importance of increasing the availability of organs for transplantation.

It sometimes is hard for me to realize today how sick I was when I was a baby, not even 2 years old, and in desperate need of a new

liver. I am sure my family has very clear memories of their worries and their hopes and their prayers.

Fortunately, the gift of life was available for me, but more than 1,000 residents of Ohio are waiting right now for a transplant, not knowing whether the gift of life is going to be available for them. Can you imagine how the families of all these people must feel?

We have great medical centers in Ohio. In Cincinnati, where I got my transplant, at Ohio State in Columbus, in Cleveland, transplant surgeons at these Ohio centers perform this miracle operation every day. The doctors are available. The organs are not.

If every Ohio family talked about the miracle of transplantation, they all obviously would hope an organ would be available if one of them needed it. Well, the Golden Rule says it is better to give than to receive. The two parts, giving and receiving, are linked. Every family might be in a position some day where it would be hoping to receive. Every family ought to be willing to give.

I think the First Family Pledge idea, getting families to all talk about the miracle of transplantation and to all agree as a family to be organ donors, is the best hope for the thousands of people waiting. I would like to thank all the Members of Congress, especially Congressmen Brown and Strickland, who are members of the subcommittee, and Congressmen Oxley and Sawyer, who are members of the full Commerce Committee, and Senators DeWine and Voinovich, and a half a dozen other members of the Ohio Congressional delegation who are supporting the First Family Pledge. Thank you.

Mr. BILIRAKIS. Thank you so much. I think if every American had the privilege to hear your story the way we do, virtually all would be taking the First Family Pledge. Of course, we take the pledge, but we also have to follow up and do what we have pledged to do, and that is something that is so important.

I just have one question very quickly. We do not want to keep you much longer. Do any of you know other children, friends or other children who will need a transplant or who need a transplant? Do you know any, Cynthia?

Ms. GUILLEMIN. No.

Mr. BILIRAKIS. No, you do not know any. What would you tell them if you knew, if one of your friends, one of your neighbors, needed a transplant? What would you tell those children? How would you make them feel good? Do any of you have an answer to that? Abbey Lynn, Cynthia, Jamar? No? Okay. It is not the first time I have raised a question from up here and not gotten an answer.

Mr. BILIRAKIS. Any further questions from members of the subcommittee?

[No response.]

Mr. BILIRAKIS. Thank you so very much. You are real heroes in our eyes.

You are excused. Thank you. Good luck to you.

The next panel consists of Mr. John Campbell, Executive Director of LifeLink; Mr. Howard M. Nathan, President of the Coalition on Donation; Dr. Amadeo Marcos, Assistant Professor of Surgery, Medical College of Virginia—I wish you would all come forward as we call your names—Dr. Joshua Miller, President of the American

Society of Transplant Surgeons, University of Miami School of Medicine; Dr. John F. Neylan, American Society of Transplantation; Dr. Robert A. Metzger, Medical Director and Transplant Physician, Translife at Florida Hospital in Orlando; Dr. Robert S.D. Higgins, Director of Thoracic Organ Transplantation, Henry Ford Hospital, Detroit, Michigan; and Mr. Joseph L. Brand, Chairman of the National Kidney Foundation, Office of Scientific and Public Policy, Arlington, Virginia.

Gentlemen, your submitted written statements are a part of the record. I understand the green light does not go on, but the red light does, so I will turn on the 5-minute clock, and hopefully you will stay as close to that 5 minutes as you can. I do not want you to cutoff right in the middle of a thought, however.

I might add that the opening statements of all members of the subcommittee are a part of the record, without objection.

We will kick it off with Mr. Campbell, if you would pull the microphone over, John, closer to you.

STATEMENTS OF JOHN R. CAMPBELL, EXECUTIVE DIRECTOR, LIFELINK FOUNDATION; HOWARD M. NATHAN, PRESIDENT, COALITION ON DONATION, DELAWARE VALLEY TRANSPLANT PROGRAM; AMADEO MARCOS, ASSISTANT PROFESSOR OF SURGERY, MEDICAL COLLEGE OF VIRGINIA; JOHN F. NEYLAN, AMERICAN SOCIETY OF TRANSPLANTATION; ROBERT A. METZGER, MEDICAL DIRECTOR, TRANSPLANT PHYSICIAN, TRANS LIFE AT FLORIDA HOSPITAL; ROBERT S.D. HIGGINS, DIRECTOR, THORACIC ORGAN TRANSPLANTATION, HENRY FORD HOSPITAL; JOSHUA MILLER, PRESIDENT, AMERICAN SOCIETY OF TRANSPLANT SURGEONS, DEPARTMENT OF SURGERY, UNIVERSITY OF MIAMI SCHOOL OF MEDICINE; AND JOSEPH L. BRAND, CHAIRMAN, OFFICE OF SCIENTIFIC AND PUBLIC POLICY, NATIONAL KIDNEY FOUNDATION

Mr. CAMPBELL. Thank you, Mr. Chairman. Thank you, ladies and gentlemen. I am John Campbell and I am here on behalf of LifeLink Foundation, which operates four of the Nation's 62 organ procurement organizations, LifeLink of Florida, LifeLink of Southwest Florida, LifeLink of Georgia, and LifeLink of Puerto Rico.

In the last 10 years, LifeLink's programs have experienced success in increasing organ donation which is far greater than the national average. We believe the success is due to unique programs at LifeLink which could be exported to other areas of the country to increase organ donation and save lives.

This year, LifeLink of Florida procured transplantable organs from 40 donors per million population, the highest rate in the Nation. This is the standard by which OPOs are currently judged. The national average is some 20 donors per million population.

We are not here to say that LifeLink's programs can double the supply of organ donors in this country, but we are here to say and to report on the increases in donations that were achieved with LifeLink's programs and to briefly identify those programs.

First, about those successes. In 1989, 63 organ donors were procured in Tampa at LifeLink of Florida. The next year, we implemented new programs designed to increase organ donation. In 3

years, organ donation increased by 46 percent. Last year, 112 organ donors were procured at LifeLink of Florida, a 78 percent increase over 1989. Over that 10-year period, then, 943 more organs were made available for transplant than if these increases had not occurred.

But in trying to export these programs, in 1993, the program was implemented in most of the State of Georgia. As of last year, the LifeLink of Georgia program had increased donation by 94 percent, from 67 donors to 130 donors. More importantly, in 1996, LifeLink of Georgia was awarded the service area that was formerly served by the Medical College of Georgia, which had been decertified for failing to meet the minimum criteria established by HCFA. In 1 year, this area of 2 million persons in eastern Georgia went from 22 organ donors to 42 organ donors, a 91 percent increase. Last year, the increase was 118 percent, to 48 donors.

In brief, LifeLink's program consists of three strategies. We first simplify the donation process. LifeLink and its eye and tissue bank partners have always employed a unified approach to donor referral with a 24-hour shared in-house operator system, whereby only one agency contacts the hospital. HCFA deserves credit for implementing some of these changes as one of the Medicare conditions of participation last year.

Also, there is virtually no competition for tissue and eye donors in LifeLink's hospitals. We believe that the current state of aggressive competition among eye and tissue banks in many parts of the country may decrease organ and tissue donation. We took the extraordinary step at LifeLink of giving up our eye bank to a competing agency for no remuneration so there would be only one eye, tissue, and organ bank in our Florida service area. It may be that exclusive service areas for eye and tissue banks should be awarded as they are to organ procurement agencies.

Second, we increased our responsibility for hospital contact and donor consent rates. LifeLink has had required referral in our hospitals for many years, and this has also become part of the new HCFA COP and has already increased organ donation this year. But we also implemented the system of designated requestors, employees highly skilled in meeting the needs of donor families when requesting organ donations. Our consent rates are among the Nation's highest.

Also, in Georgia, we created the Minority Donation Education Project to address the low consent rate among African Americans. LifeLink's minority consent rate has become nearly 50 percent, which we believe is significant.

Third, we established a strong hospital liaison and organ procurement organization management program. We focused on a service-oriented approach to hospital development and hired applicants with communications and public relations backgrounds. But most importantly, we hired significant numbers of these employees. We have in the State of Georgia 20 full-time hospital development employees for the 7 million persons in that State. We have six full-time hospital development employees for the 2.8 million people in our Florida service area. We do not believe any organ procurement organization in the United States staffs at near these levels.

And last, LifeLink is independent of its transplant centers in Georgia, Florida, and Puerto Rico. Although we have the appropriate and required transplant center representation on our governing and advisory boards, a majority of our board members come from the community. In this way, LifeLink is free to establish reasonable programs to increase organ donation without undue concern about the financial impact of these programs on its transplant centers.

In conclusion, our professional education and hospital service programs have allowed LifeLink to meet the needs of donor and recipient families in our service area. We provide a large number of organs for transplant in Florida, but significantly, also for the rest of the country. We would be glad to share our program with any agency, if that would help achieve a similar increase in donation. Thank you, Mr. Chairman.

[The prepared statement of John R. Campbell follows:]

PREPARED STATEMENT OF JOHN R. CAMPBELL, SENIOR VICE PRESIDENT/GENERAL COUNSEL, LIFELINK FOUNDATION

My name is John Campbell, and I am here on behalf of LifeLink Foundation, which operates four of the nation's 62 Organ Procurement Organizations (OPOs), LifeLink of Florida, LifeLink of Southwest Florida, LifeLink of Georgia, and LifeLink of Puerto Rico. Along with my employers and co-workers, I have helped to manage these programs for the last ten years. In those ten years, LifeLink's programs have experienced success in increasing organ donation that is far greater than the national average. We believe this success is due to unique circumstances and unique programs at LifeLink, circumstances and programs which could be exported to other areas of the country to significantly increase organ donation and save lives.

Ladies and gentlemen, you are aware of the dilemma we face: 65,000 Americans wait to receive a life-saving gift from some 5,400 organ donors this year. Those donors produce some 20,000 transplants, leaving 45,000 Americans to wait their turn, and many to die waiting. Unfortunately, the number of organ donors has not significantly increased in the last decade. However, LifeLink has experienced significant increases in organ, tissue, and eye donation in its service areas. These increases are tied to programs of management, hospital education, public education, and community involvement.

SUCCESSSES OF THE LIFELINK PROGRAM

This year, LifeLink procured transplantable organs from 40 donors per million population, the highest rate in the nation. (See Attachment). This is the standard by which OPOs are currently judged. The national average is some 20 donors per million population. We are not here to say that this means LifeLink's programs can double the supply of organ donors in this country. The number of potential organ donors is fixed, and all we can do is increase our efficiencies of identifying and medically managing such cases, as well as optimizing our consent rates. We are here to report on the increases in donation that were achieved with LifeLink's programs, and to briefly identify those programs.

In 1989, 63 organ donors were procured in Tampa, at LifeLink of Florida. The next year, we implemented certain programs designed to increase organ donor identification and organ donation, which are described below. In 3 years, organ donor referrals increased by 400%, and organ donors increased by 46% to 92. Last year, 112 organ donors were procured at LifeLink of Florida, a 78% increase over 1989. And, over that 10 year period, 943 more organs were made available for transplant than if these increases had not occurred. It is important to note that LifeLink was already one of the top performing OPOs when this process started.

In 1993, the program was implemented in most of Georgia, including Atlanta. From 67 organ donors in 1992, the LifeLink of Georgia program increased to 130 donors in 1998, an increase of 94%. More importantly, in 1996 LifeLink of Georgia was awarded the territory of Eastern Georgia, which had been decertified for failing to meet the minimum criteria established by HCFA. In the first full year of operation, this area of two million persons went from 22 organ donors to 42 organ donors, a 91% increase. In 1998, this area produced 48 organ donors.

In addition to the increases in organ donation noted above, LifeLink has experienced significant increases in eye and tissue donation with our tissue banking partners, to some of the highest levels reported in the country.

STRUCTURE OF THE LIFELINK PROGRAM

LifeLink's program has been shared with any OPO or agency with an interest, here and with visitors from Asia, India, South America and England. In brief, it consists of three key strategies which we hope can be replicated in other agencies and other states:

1. Simplify the Donation Process

- For many years, LifeLink and its eye and tissue bank partners have employed a unified approach to referral in all hospitals. Our approach uses a 24-hour shared; single, in-house transplant operator system, whereby only one agency contacts the hospital. The Health Care Financing Administration (HCFA) deserves credit for implementing some of these changes as one of the Medicare Conditions of Participation (COP) last August.
- LifeLink believes that there should be no competition for tissue and eye donors in hospitals, and *that the current state of aggressive competition in many parts of the country may decrease donation.* We took the extraordinary step of giving up our eye bank to a competing agency, for no remuneration, so there would be only one eye, tissue, and organ bank in our Florida service area.
- If exclusive service areas for eye and tissue banks were assigned and awarded as they are to organ procurement agencies, we believe far less confusion and negative incidents would result.

2. Accept the Responsibility of Contact and Consent

- LifeLink implemented Required Referral in 97 percent of our hospitals. This has also become part of the new HCFA COP.
- LifeLink implemented a system of "designated requestors," employees highly skilled in meeting the needs of donor families when making the request for organ donation. Our consent rates for tissue and organ donation are among the highest in the nation.
- In Georgia, LifeLink created the Minority Donation Education Project (M.D.E.P.) to address the low consent rate among African-Americans through the education of health care workers about donation. LifeLink is also a local contractor with the Minority Organ and Tissue Transplant Education Program (MOTTEP), which provides public education about donation to minority communities. LifeLink's minority consent rate is nearly 50 percent, which we believe is significant.
- LifeLink has instituted a chaplain's program, with on-staff clergy who are active in our community churches and with hospital based chaplains to educate them about organ and tissue donation.

Establish a Strong Liaison and Management Program

- LifeLink focused on a service-oriented approach to hospital development and medical examiner development, and hired applicants with communications and public relations backgrounds. Most importantly, we have significant numbers of these employees, and we have expended the resources required to ensure the optimal amount of hospital referrals and feedback. We have 20 Full Time Employees for the 7 million people in Georgia (including our MDEP staff), and 6 Full Time Employees for the 2.8 million people in our Florida service area. We do not believe any OPO in the country staffs at this level of FTEs per million population.
- LifeLink hospital development staff follow-up at the staff level in person on virtually all referrals, encouraging greater participation by nurses and physicians.
- We instituted administrative call, requiring the executive director to be on call 24-hours a day, and to be contacted on *every* organ and tissue donor to provide continuity and quality. Our Risk manager is also on call 24-hours a day, to provide input on more difficult, single organ, or "marginal" donors.
- LifeLink is independent of its transplant centers in Georgia, Florida, and Puerto Rico. Although we have appropriate and required transplant center representation on our governing and advisory boards, a majority of our board members represent the community. In this way, LifeLink is free to establish reasonable programs to increase organ donation, without undue concern about the financial impact of these programs on its transplant centers.

CONCLUSION

Our professional education program and comprehensive service system have positively impacted LifeLink's ability to meet the needs of families in our service area. We provide a large number of organs for transplant centers in Florida, and around the country. LifeLink exports a significant percentage of organs, as does the state of Florida, so our efforts help increase transplantation around the country, not just in our service area. We would be delighted to share our program with any agency or state to help them achieve a similar increase in needed organ donations.

ATTACHMENT

AOPO OPO Voluntary Survey—January 1998-December 1998
[Updated Final]

UNOS Code	OPO Name	Population Reported	Total Donors	Donors per Million
FLWC	LifeLink of Florida	2.8	112	40.00
FLUF	University of Florida	2.4	78	32.50
FLFH	TransLife	2.4	78	32.50
NVLV	Nevada Donor Network	1.0	31	31.00
PADV	Delaware Valley Trans	9.9	298	30.10
MOMA	Mid-America Transplant Assoc	4.2	124	29.52
TNMS	Mid-South Trans. Foundation	1.7	49	28.82
WISE	Wisconsin Donor Network	2.2	63	28.64
WNCP	Lifsource-Upper Midwest OPO	6.1	174	28.52
WIUW	University of Wisconsin	3.1	87	28.06
National Average	21.70

Mr. BILIRAKIS. Thank you so much, Mr. Campbell.
Mr. Nathan?

STATEMENT OF HOWARD M. NATHAN

Mr. NATHAN. Good morning, Mr. Chairman. Thank you for holding these hearings. It is an important topic.

My name is Howard Nathan. I am the Executive Director of Delaware Valley Transplant Program, the regional nonprofit organization in the eastern half of Pennsylvania, southern New Jersey, and Delaware. I am also President of the Coalition on Donation, which is a national alliance of all the transplant community focusing on grassroots, primary education, public education about organ and tissue donations.

I will first talk about my experience as an organ procurement organization executive director. My organization represents 3,200 people waiting for transplants in our region at 12 hospitals in the greater Philadelphia area. In 1997 and 1998, DVTP was the most active OPO in the United States, coordinating a record number of organ donors, resulting in 1,844 life-saving transplants.

The Coalition on Donation, through its world class talents from advertising and communications, including the Ad Council, has communicated its message throughout the country so that more and more people are signing organ donor cards and has cooperated with many national organizations in partnership to increase organ donation.

One of the things that I would like to talk about today, which Congressman Greenwood referred to, was the law that was passed in Pennsylvania in 1994. It was called Act 102. It was the most comprehensive law on organ donations, to encourage organ donations. The first part of it, called routine referral, was enacted and

cooperation occurred with all the hospitals in Pennsylvania, resulting in a 43 percent increase in organ donations and a 53 percent increase in transplants, compared to the year prior to its implementation. It has now been implemented nationally through the Medicare conditions of participation of hospitals and preliminary data shows that a 5.5 percent increase in donations have occurred since its implementation as recorded by the number of organ donors last year.

Equally important are not only systems in hospitals but providing public education to increase the awareness of the donor option.

One of the other conditions of the Pennsylvania law was the Organ Donor Awareness Trust Fund, which raised voluntary contributions from driver's license contributions to increase public education initiatives. Congressman Greenwood indicated that one of those provisions, which was released yesterday in the media, aids organ donor families for funeral expenses. It has not been implemented yet. It will be implemented in the fall.

In addition, there is a computerized registry that registers people's wishes through their driver's license program, and since 1995, more than 3 million Pennsylvanians have been registered, which allows the organ procurement organization access to this information 24 hours a day.

Increasing consent rates is the key now, once we have the systems in place to hear about all potential donors from hospitals. That is why I have taken the Presidency of the Coalition on Donation for the past several years, to increase this message, the "share your life, share your decision" message to the country. There are many examples of cooperation and partnerships with organizations throughout the country. It is supported by the United Network for Organ Sharing. The transplant community has funded this effort, but more funding is needed to communicate this message to the public.

The Ad Council is one of our partners and has communicated this message to 30,000 media outlets each year for the past 4 years. The James Redford Institute for Transplant Awareness, led by Jamie Redford, a liver transplant recipient, created two films that will be distributed this year to educate kids about organ transplantation and donation, which will be distributed by the Coalition.

One of the more visible campaigns was the Michael Jordan campaign, with which many of you are probably familiar. More than 12 million organ donor cards with Michael Jordan's picture have been distributed nationwide and more than a million posters have been distributed to kids throughout the country.

So it is a combination of these two factors, organ procurement efficiency, as my colleague, Mr. Campbell, talked about, cooperation with hospitals in each State, and making sure that every family is offered that option and hopefully that they are predisposed by having the discussion while they are alive and well at the dinner table to talk about this "share your life, share your decision" message.

Ongoing public education is the key to increasing organ donation. We need more of a commitment to moneys to public education to make sure that this message is carried out in every American household. Additionally, suggestions for geographic centralization of donor information, such as a driver's license registry, would be

very helpful in making sure that people's wishes are registered, but most importantly, to make sure that then they follow up with the discussion with their family.

Thank you very much, and I appreciate the opportunity.
[The prepared statement of Howard M. Nathan follows:]

PREPARED STATEMENT OF HOWARD M. NATHAN ON BEHALF OF DELAWARE VALLEY
TRANSPLANT PROGRAM AND COALITION ON DONATION

I am Howard M. Nathan, the Executive Director of Delaware Valley Transplant Program ("DVTP"). DVTP is the nonprofit organ procurement organization ("OPO") that serves patients and hospitals in Eastern Pennsylvania, Southern New Jersey, and Delaware and has a population base of 9.8 million. For 25 years, DVTP has served more than 160 acute care hospitals in the greater Philadelphia region; it has been certified by the Health Care Financing Administration ("HCFA") since 1988 as the OPO for its service area and has been a Medicare provider since 1979, when HCFA assigned DVTP independent OPO provider status for reimbursement purposes. DVTP currently serves nearly 3,200 patients awaiting life-saving organ transplants at 12 regional transplant hospitals. In addition, it has cooperative relationships with 4 regional eye banks and 3 tissue banks. DVTP consistently has been recognized as one of the nation's top performing OPOs. In 1997 and 1998, DVTP was the most active OPO in the U.S., coordinating a national record number of organ donors (291 and 298 respectively) for any OPO service area in the United States resulting in 1,844 life saving transplants.

I am also appearing today as President of the national Coalition on Donation ("Coalition"). The Coalition is an alliance of the entire transplant community, including 48 national organizations and 50 local grassroots coalitions with the primary mission of educating the public about organ and tissue donations and creating a willingness to donate. You may be familiar with the Coalition's unified national message, "Share Your Life, Share Your Decision" which was developed by the Ad Council and utilized in the Coalition's highly visible Michael Jordan public education campaign, as well as the Ad Council campaigns on organ and tissue donation. Numerous partnerships with world class talents from other advertising and media agencies have been formed so that all organizations in the Coalition have the opportunity to utilize these talents and deliver a common message to the public. Another such example, supported by Congress' efforts in enacting the National Donor Card Insert Act, the Coalition worked with the U.S. Department of Treasury and Department of Health & Human Services in 1997 to provide 70 million people the opportunity to indicate their wish to become organ or tissue donors by including donor cards in the envelopes that contained IRS tax refunds.

My other experiences in transplantation include past President of the Association of Organ Procurement Organizations ("AOPO") and 3 times elected to the Board of the current Organ Procurement and Transplantation Network ("OPTN") contractor, the United Network for Organ Sharing ("UNOS").

Working with DVTP and our elected representatives, as well as other organizations, such as the Coalition on Donation, "OPO, and UNO" for more than 20 years, has granted me the opportunity to work closely not only with transplant hospitals and OPOs, but with donor families and transplant recipients at both the local and national levels. I understand that a single unified message regarding donation must be communicated through comprehensive public education initiatives. This in conjunction with providing all potential donor families with the donor option is critical to combating the organ donor shortage.

I. ROUTINE REFERRAL—ENSURING ALL FAMILIES ARE ADVISED OF THE DONOR OPTION
DVTP's Experience with Pennsylvania's Routine Referral Law Resulted in a Dramatic Increase in Organ Donation.

In 1994, Pennsylvania enacted Routine Referral legislation which provides (i) for the routine referral of all hospital patients' deaths to the OPO in order to determine suitability for anatomical donation, and (ii) for OPO initiation of and participation in the family discussion regarding the donor option. Implementation of this law resulted in unprecedented growth in the number of organ donors in DVTP's Pennsylvania service area. Just 4 years after enactment of the law, the number of donors that DVTP coordinated in its Pennsylvania service area increased by 43%. Similarly, the number of actual organ transplants that DVTP coordinated in 1998 was 53% greater than the number DVTP coordinated in 1994. This growth occurred at a time when organ donations nationally increased an average of less than 2-3% a year.

Routine Referral is Being Implemented Nationally.

The Pennsylvania Routine Referral Law and DVTP's partnership with the health care community in Pennsylvania served as a national model for Routine Referral rules that were promulgated and applied nationally to all Medicare and Medicaid participating hospitals as of August, 1998. Those rules, which members of Congress, including members of this Committee chose to have implemented last year (notwithstanding Congress' decision to delay the implementation of rules regarding the organ procurement and transplantation network) are already having an effect.

Preliminary data reveals that national organ donation rates for calendar year 1998 are approximately 5.5% higher than the donation rates for calendar year 1997. The most significant increases appear to have occurred the last four months of 1998; the four months following the effective date of the federal Routine Referral rules. I anticipate that just as DVTP's Pennsylvania donation rates have continued to rise, the national rates will continue to rise with Congress' full support of this federal Routine Referral standard and the continued cooperation of the medical community.

The 1994 Pennsylvania Routine Referral law went beyond advising families of the donor option at the time of a loved one's death. Equally significant, it recognized the critical issue of providing public education and increasing awareness of the donor option. That law provided for the establishment of an Organ Donor Trust Fund. The Trust Fund monies, funded through voluntary contributions made by residents through state tax refunds, as well as check offs on drivers' license and motor vehicle registration applications, are committed to public education initiatives.

Finally, the Pennsylvania law established a central computerized registry of individuals who have elected to have the organ donor designation included on their driver's license. This enables the OPO to have immediate confidential access to information regarding a patient's own wishes regarding donation. Since January 1995, over 3 million Pennsylvanians have designated their wishes regarding donation on their drivers' licenses and that information is included in the central registry. Several other states, including Delaware, Florida, Georgia, Illinois, Louisiana, Maryland and Missouri have similar registries.

II. INCREASING AWARENESS WILL INCREASE ORGAN DONATION

Increasing consent rates requires significant public education and information. This process of disseminating information must take place well before the tragic event which may result in a loved one's death. Education and discussions regarding the gift of life must occur at a time when the individual has the opportunity to make this decision regarding him or herself. Congress and this nation have supported patient autonomy and decision making. The optimal time to make decisions regarding donation is in the home, outside the hospital setting and well before traumatic end of life decisions are required to be made. The decision regarding organ donation is one that can easily be made if individuals have accurate information about donation. It is a decision that simply requires thoughtful consideration of the issues and a designation on a driver's license or donor card. Although it requires no further legal action by the donor, it is imperative that the wishes of the individual be clearly communicated to his or her next of kin so that they will be knowledgeable about the choice that has been made.

The Coalition on Donation was created in 1993 by the transplant community to bring the issue of donation to the forefront and to provide a unified message to the public regarding organ donation. The single message "Share Your Life, Share Your Decision" provides the action steps needed for an individual to make a decision and share it with his or her loved ones. The literature demonstrates that ongoing public education does bring organ donation into the mainstream and families are more comfortable discussing their wishes regarding donation now that donation is no longer shrouded in myth. It is an option embraced by the various cultural and religious groups and is supported because donation does save lives.

The Coalition on Donation serves as an example at many levels for the type of collaborative relationship that is critical if we as a nation are to successfully combat the donor organ shortage.

- The United Network for Organ Sharing ("UNOS") has collaborated since the Coalition's inception. UNOS and the transplant community have supported the Coalition and its educational campaigns by providing funding for the Coalition's staff and through the voluntary assessment of UNOS members and the transplant community.
- The Ad Council, in conjunction with its tremendous talent and more than 50 years of communication expertise, has created four campaigns that have been distributed to more than 30,000 media outlets in the past six years.

- The James Redford Institute for Transplant Awareness developed a film to educate teens about donation and transplantation and has partnered with the Coalition to distribute the film nationwide for the 1999-2000 school year.
- Through the Coalition, Congress and the transplant community successfully partnered to distribute more than 60 million donor cards in 1997 as provided by the National Donor Card Insert Act.
- The Coalition and UNOS' public education campaigns were considered so essential to overcoming the organ donor shortage that the federal government also adopted the Coalition's "Share Your Life. Share Your Decision." Michael Jordan public education campaign.
- The U.S. Postal Service working with the Coalition to promote the issuance of and distribution of an organ donor awareness stamp in 1998.
- More recently, after considering numerous national charitable organizations, a major motion picture studio will soon announce it has chosen UNOS and the Coalition as recipients of a PSA competition, which included high profile ad agencies to develop public education pieces on organ donation and transplantation.

The health care community must also continue to receive updated information on donation and transplantation advancement and initiatives. One example of a jointly developed educational tool for the medical community is the recently published Journal of the Association of Critical Care Nurses. That Journal edition supported by both UNOS and the Critical Care Nurses Association reports on the medical advancements regarding the medical suitability of potential organ donors after cardiac death being made which allow a greater number of families to be offered the donor option.

III. PARTNERING FOR THE FUTURE—ACTION PLAN TO REDUCE THE ORGAN DONOR SHORTAGE

These historical collaborative efforts demonstrate that steps to decrease the gap between the number of available organs and the number of people on the waiting lists can be undertaken. A comprehensive national approach to educating and informing the public must be supported. We need to give Americans the ability to easily designate their wishes without burdening the decision-maker. In all hospitals, we must support Routine Referral to ensure that all potential donor families have considered the donor option at or near the time of the death of a loved one.

This comprehensive approach must include:

1. A system of efficiently operating OPOs given the responsibility of discussing the donor option with families at or near the time of death of a loved one.
2. Ongoing public education and awareness programs designed to inform families about organ and tissue donation and to encourage decision-making long before the family must deal with the traumatic circumstances surrounding a loved one's death. The donor decision is best decided by the individual in the light of life, not by the family in the darkness surrounding death.
3. The ongoing commitment of monies to public education efforts. This can be accomplished through a variety of mechanisms, including a voluntary contribution made by taxpayers of a portion of any federal tax refund. Similar to the Pennsylvania law, these funds could be earmarked for specific public education and awareness programs designed to promote organ and tissue donation.
4. Support of the geographic centralization of donor information that is immediately available to the OPO. The establishment of state registries or regional will ensure that the wishes of a decedent as designated on a drivers license or other registration are known and honored. This can be accomplished through central state registries such as the ones supported by Pennsylvania, Delaware, Florida, Georgia, Illinois, Louisiana, Maryland and Missouri.

It is through initiatives such as those described above that we can expect to combat the organ shortage.

Thank you for allowing me to provide testimony to this Committee.

Mr. BILIRAKIS. Thank you, Mr. Nathan.
Dr. Marcos?

STATEMENT OF AMADEO MARCOS

Mr. MARCOS. Thank you. Mr. Chairman, members of the committee, on behalf of the Virginia Commonwealth University Medical College of Virginia, I would like to talk to you today about the

topic of living donor liver transplants. The waiting list, as you all know, has grown out of proportion——

Mr. BILIRAKIS. Would you pull the microphone closer to you, Dr. Marcos? Thank you.

Mr. MARCOS. The waiting list has grown out of proportion. Up to April 1999, 12,648 patients were waiting for livers. Despite the significant efforts to increase awareness and need for donation, the number of donors for livers remains static, with around 4,000 cadaveric livers available, which will mean that 10 to 15 percent of the patients waiting on that list are going to die within a year.

Transplant decisions have come with strategies to aim and to resolve this problem. Some solutions have been reducing the size of the liver, splitting the livers, and the one I am going to talk to you about today, which is the living donor liver transplant. This technique was started in the 1980's in an effort to alleviate the shortage of organs at that time for pediatric recipients. The main disadvantage of this operation is putting a healthy donor at risk, which will always be an ethical concern.

But besides the availability, which is the main advantage of this technique, the biggest constraints imposed by cadaveric donation is time. Despite advances in organ preservation, the viability of the liver decreases or declines after procurement and it is seriously compromised after 12 hours. This, of course, is a good advantage of the living donor.

The living donor permits to screen and do more tests on the donors which has no limited time and rule out 100 percent infectious diseases like HIV and hepatitis. The psychological advantages of a living donor transplant, although they are difficult to quantitate, are undoubtedly significant. The opportunity to help save the life of a loved one gives donors a great deal of personal satisfaction and some degree of control over a situation that would otherwise be left entirely to chance. Recipients take comfort in the fact that the organs come from a loved one or a known one and this could translate into better care of those organs.

Finally, our preliminary figures show that living donation may actually be more cost effective than cadaveric donation.

While this technique has significantly impacted on pediatric transplantation, its use for adults has been limited. Surgeons in Japan at the beginning of the 1990's started doing right lobe living donor transplants with very good results.

Ourselves, at the Medical College of Virginia, started doing this technique about a year ago and since have performed about 22 adult-to-adult right lobe living donor transplants. The main driving force behind us has been the dramatic decrease of cadaveric organs in our organ procurement organization, OPO, by 40 percent from the previous year. Twenty percent of this reduction was a result of sending organs for sharing within our region to other OPOs. As new laws for organ allocation and the development of new liver programs in the region could potentially increase this reduction of cadaveric offers, the living donor becomes a significant life-saving option for our patients. Nowadays, 45 percent of patients that get transplants at the Medical College of Virginia do so through a living donor.

Although long-term results and follow-up is lacking, our initial results are extremely promising. Most importantly, there have been no complications on the donors. They all have left the hospital within a week and returned back to their own activities. When asked if they would do it again, they all say yes. The recipients also have had good results and we have performed this procedure both in high urgency or elective circumstances with excellent results.

The number of patients awaiting liver transplantation is likely to continue to increase, at least over the next decade. While the incidence of many liver diseases is expected to be stable, the incidence of hepatitis is increasing dramatically. A significant number of patients infected with hepatitis B and C will go on to develop end-stage liver disease, requiring transplantation. Current data also suggests that early stage cancer can be treated with transplantation, which in itself will shorten the availability of organs.

In summary, the waiting lists will continue to increase. The number of cadaveric donations has been relatively static, leaving a significant number of people to die each year while waiting for transplantation. Living donor liver transplantation has been widely accepted by the transplant community and general population as an appropriate means of expanding the donor pool for pediatric recipients. Early data suggests that this technology can be safely performed in adult recipients, although continued critical review of the results is warranted. For every patient that receives a liver from a living donor, a cadaveric organ can become available for a patient waiting on the list.

I want to thank the Commerce Committee and the Institute of Medicine for the opportunity to participate in this hearing. Thank you.

[The prepared statement of Amadeo Marcos follows:]

PREPARED STATEMENT OF AMADEO MARCOS, MEDICAL COLLEGE OF VIRGINIA

Good Morning Chairman Bilirakis and Members of the Subcommittee on Health and Environment. It is indeed a pleasure for me to be here with you to share the successes that we, at Virginia Commonwealth University's Medical College of Virginia, have had in the area of organ transplantation. Specifically, I would like to focus on the living-liver transplant program.

Diseases of the liver are diverse and indiscriminately affect people of all ages and races. Most conditions are unfortunately, progressive and almost uniformly fatal. Because the liver serves so many indispensable functions, medical management of the complications of end stage liver disease is complex and ultimately fails, resulting in death of the patient unless the process is interrupted by transplantation.

Significant advances in the field of organ transplantation over the last few decades have resulted in dramatic improvements in survival and quality of life following transplantation. As a result of these innovations, early transplantation has become the treatment of choice for most acute and chronic liver diseases and a variety of genetic disorders.

With this success, the waiting list has grown far out of proportion to the number of organ donations. There were 12,648 patients listed for liver transplantation by April 1999. Despite significant efforts to increase awareness of the need for organ donation, the numbers have been relatively static for several years. Only about 4000 cadaveric livers become available for transplantation each year, leaving as many as 10 to 15% of the waiting list to die before an organ becomes available.

The function, vascular supply, and anatomical position of the liver impose significant limitations on the size of the donor organ that can be transplanted. The liver must be large enough to meet the early post-operative needs of the recipient to overcome the results that result from the process of transplantation. Unlike the kidney or the pancreas, the specialized function and blood supply to the liver necessitate its transplantation into its natural anatomic position, limiting a graft to the size of

the cavity. The size limitation has been particularly problematic for infants and children needing transplants, as most cadaveric donors are adults.

Organs for pediatric recipients have always been relatively scarce, and several innovative surgical techniques were developed in response. Size reduction involves "trimming" an adult size liver down to an appropriate size for a child, while the remnant is discarded. Though this wastes a portion of the viable organ, it is an option if another organ of appropriate size is unavailable. Split liver transplantation divides the organ into two smaller segments, potentially doubling the number of patients that benefit from single cadaveric organ. Donor organs for splitting must possess certain characteristics that are, unfortunately, all too rare. Rather than significantly increasing the availability of organs, split liver transplantation effectively diverts the supply from adults in need of organs to children.

Living donor transplantation was developed in the late 1980's in an effort to definitively alleviate the shortage of organs for pediatric recipients without contributing to the shortage for adults. Using surgical techniques similar to those for resection of liver tumors, a segment of the liver is removed from a willing donor, usually a parent, and transplanted into the recipient. This technique has been widely applied to the pediatric population over the last decade with over one thousand successful procedures reported to date. With refinements in surgical techniques, living donor transplantation actually results in better patient and graft survival. The safety of the donor has been well established for the type of resection generally employed for pediatric recipients, with only one death and a handful of potentially life threatening complications reported worldwide.

The main disadvantage of using a living donor is the ethical problem of subjecting a healthy donor to a surgical procedure of significant magnitude. When compared with cadaveric donation it may pose some advantages.

Besides availability, one of the biggest constraints imposed by cadaveric donation is time. Despite advances in organ preservation, the viability of the liver declines immediately following procurement and is seriously compromised after 12 hours, limiting screening of donors and preparation of recipients. The use of living donors essentially removes this time constraint.

The immediate and long term function of transplanted livers is directly related to "cold storage" time. Organs from living donors are transplanted almost immediately, essentially eliminating "cold storage", thereby optimizing function. The recovery time, number of post operative complications, and chances of survival following liver transplantation are also related to the preoperative condition of the recipient. Significant decompensation adversely impacts recovery and long term survival. Organs from living donors are available at the time transplantation is medically indicated, without further deterioration of the recipient waiting for a cadaveric liver. This has been the main advantage of this technique.

Although screening tests for viral infectious diseases are remarkably accurate and there have been relatively few reports of transmission of the more serious diseases in recent years, there are false negatives and early infections which may not be detected by standard tests. More meticulous testing for infectious diseases, including HIV and hepatitis, is impractical for cadaveric donors and information regarding their lifestyle is generally lacking. More sensitive testing and screening can be performed with living donors, at least theoretically decreasing the risk of transmission of these diseases. Subclinical bacteria and fungal infections are relatively common in cadaveric donors, contributing to post transplant complications. Living donors are unlikely to harbor a subclinical infection and transplantation could be delayed pending resolution.

The psychological advantages of living donor transplantation, although difficult to quantitate, are undoubtedly significant. The opportunity to help save the life of a loved one gives donors a great deal of personal satisfaction and some degree of control over a situation that would otherwise be left entirely to chance. Recipients take comfort in the fact that the source of their graft is a trusted friend or relative and a new bond is undoubtedly created between donor and recipient that could translate into better care of the given organ.

Finally, our preliminary figures suggest that living donation may actually be more cost effective than cadaveric donation.

While this technique has had significant impact on pediatric transplantation, its application to adults in need of transplantation has been limited by size of the segment of liver that is obtained. The original technique involves resection of only a small portion of the left side of the liver, inadequate for transplantation into adults. We knew from the trauma of cancer literature that resection of up to 80% of liver mass is well tolerated by otherwise healthy individuals and is technically feasible. The liver, unlike other solid organs, is uniquely able to regenerate to a predetermined size, making these extensive resections possible without significant risk of

liver failure. There has been hesitation to perform these more extensive procedures, however, because of the higher potential for complications in donors, including bleeding, infection, and cardiac and pulmonary events. Surgeons in Japan, where cadaveric donation was not an option until recently, were the first to report donor resections of the entire right side of the liver, representing approximately 60% of liver mass, in the early 1990's. The initial procedures, despite being performed in desperation, gave good results with minimal donor complications.

The living donor liver transplant program at the Medical College of Virginia Hospitals was started just over one year ago. We have since performed 22 adult-to-adult right lobe living donor transplants. The main driving force behind this has been the dramatic decrease of cadaveric organs in our Organ Procurement Organization (OPO) by 40% from the previous year. 20% of this reduction was a result of sending organs for sharing from our OPO to others within our region. As new laws for organ allocation and the development of new liver programs in the region could potentially increase this reduction in cadaveric offers, the living donor becomes a significant life saving option for adult patients on our waiting list. Living donor transplants now represent almost 45% of all the liver transplants we perform at the Medical College of Virginia.

Although long-term follow up is lacking, our initial results are extremely promising. Most importantly, there have been no serious donor complications. None have required transfusion of banked blood and all have been discharged from the hospital within 10 post-operative days. None have required reoperation or readmission to the hospital, and all promptly returned to their previous activity level. Imaging of their livers has confirmed rapid regeneration to its previous size. No one has expressed regret for having undergone surgery.

The results in recipients have also been excellent. We have performed these procedures in both high urgency and more elective circumstances with outcomes similar to those obtained from cadaveric transplantation. All of the grafts have functioned well after transplant. Survival is comparable to cadaveric transplantation with only 3 deaths occurring in patients who were seriously decompensated prior to transplantation. All of the deaths were attributable to infectious complications rather than surgical or graft specific factors. A majority of recipients were discharged within two weeks of surgery.

The number of patients awaiting liver transplantation is likely to continue to increase, at least over the next few decades. While the incidence of many liver diseases is expected to be stable, the incidence of hepatitis infections is increasing dramatically.

A significant number of patients infected with hepatitis B and C will go on to develop end stage liver disease requiring transplantation. Current data also suggests that early stage liver cancer can be effectively treated by transplantation. The development of more effective screening methods may result in extending the indications for liver transplantation to include more cancer patients.

In summary, the waiting list for liver transplantation has expanded out of proportion to the number of cadaveric donations and will likely continue to grow for at least the next decade. The number of cadaveric donations has been relatively static, leaving a significant number of people to die each year while awaiting transplantation. Living donor transplantation has been widely accepted by the transplant community and general population as an appropriate means of expanding the donor pool for pediatric recipients. Early data suggests that this technology can be safely extended to meet the needs of adult recipients, although continued critical review of the results is warranted.

For every patient that receives a liver from a living donor, a cadaveric organ can be made available for the next person on the waiting list.

Mr. BILIRAKIS. Thank you very much, Dr. Marcos.
Dr. Neylan?

STATEMENT OF JOHN F. NEYLAN

Mr. NEYLAN. Thank you, Mr. Chairman. I am John Neylan and I am Medical Director of Kidney Transplantation at Emory University and I am President of the American Society of Transplantation.

The AST, which has no government support, was established in 1982 and our membership, now over 1,400 members strong, is comprised of physicians, surgeons, and scientists actively engaged in

the research and practice of transplantation medicine and immunobiology. As such, the AST represents the majority of professionals in the field of transplantation in the United States today.

Over the last 30 years, transplantation of solid organs has moved from experimental to accepted therapy, with over 20,000 performed in 1998 alone. The success of this procedure has improved greatly over the last few years, with almost all solid organ recipients now enjoying an 83 to 97 percent survival rate at 1 year.

Much of this success can be attributed to research in immunosuppression and basic science that has been funded through Federal appropriations. Our better understanding of the body's response to foreign proteins has led to countless other breakthroughs throughout all areas of medical science. However, this success has brought with it some new challenges.

More and more individuals are agreeing to be placed on the waiting list for an organ transplant, and as a result, the list has increased in size by 255 percent in the last 10 years. It is an unfortunate and absolutely unnecessary fact for those in need of a transplant to go without the gift of life. There is an insufficient supply of available donors, which is far less than the growing demand.

I would like to focus my testimony on the most important issue facing the transplant community today, providing transplantable organs for patients in need. Even as we in the transplant community continue the deliberate and at times difficult discussions that surround the process of determining the optimal means for allocating a precious, though numerically inadequate, resource, we must never forget the crux of the problem and the real solution, increasing organ donation.

During the next hour, four new names will join those 58,000 individuals in this country waiting for a solid organ transplant, and by the time I get home to Atlanta this evening, 10 individuals will have died because the wait for a transplant was just too long. It is an unfortunate and absolutely unnecessary fact that we as a Nation are not living up to our potential. Too many families are turning down the option of organ donation.

But, Mr. Chairman, with increased education and improved coordination among the public and private sectors, we can improve donation rates and thus make the gift of life a reality for thousands of Americans. The AST believes strongly that Federal and State governments, providers, and the patient community need to establish a working compact directed at translating the extremely high public awareness about the value of the gift of life into a proactive national effort to actually increase organ donation. Only by working collectively with all the stakeholders involved can we successfully address this critical issue.

In addition, the AST strongly supports Congressional reauthorization of the National Organ Transplant Act, which was last reauthorized in 1990. Such reauthorization undoubtedly will help to enhance support for organ donation initiatives.

In my own State of Georgia, there are numerous examples of such good works. Many communities have rallied financial support for someone amongst them in need of a liver transplant. Through these efforts, socio-economically disadvantaged patients have received the fruits of this life-saving but costly medical miracle.

On another level, we have within our State a charitable organization entitled the Carlos and Marguerite Mason Fund, which has so far provided millions of dollars for transplant research, patient support, and also organ donation initiatives. An example of the latter is an ongoing minority outreach program which seeks through multiple interventions to enhance donation within the African American community.

At the State level, Georgia has clearly demonstrated a real and tangible financial support for organ donation by providing a discounted driver's license renewal fee to those who designate their personal support to the cause of organ donation.

Last year, the AST worked closely with Congressman Elijah Cummings to introduce and pass in the House of Representatives legislation to increase the amount of leave time available to Federal employees serving as donors. In the past, a lack of leave time has served as a significant impediment and a disincentive for individuals willing otherwise to share the gift of life. The legislation has been reintroduced into the 106th Congress and is strongly supported by our Society.

AST believes that targeted initiatives, such as Congressman Cummings' Congressional legislation, can collectively make a difference, especially those initiatives which support living donation. Indeed, programs that enhance living donation may be among the most immediate, the most effective, and the least expensive activities available to our Nation today.

As we all know, organ donation is the real answer to dealing with the dilemma of allocating and distributing this inadequate supply. In addition to our own efforts and those of the greater transplant community, the AST has consistently urged the Federal Government to take on a continued and greater leadership role in this most important component of the problem through increased research funding, increased public education and awareness campaigns, and through the implementation of the hospital participation in Medicare and Medicaid regulations.

A year and a half ago, the administration moved forward with a national organ and tissue donation initiative to encourage more families to discuss and understand their loved ones' wishes in regard to donation. Most recently, these activities have included a national donor day, and this week, a national donor recognition ceremony, to honor those individuals who have given the ultimate gift, the gift of life. These important initiatives serve to raise the national awareness and educate the public regarding the importance and critical need of their participation in the process. Such activities are helpful in the reduction of family refusal, which is the No. 1 cause of loss of potential donors today.

We all know and understand that increasing our Nation's supply of organs is the real answer to our current dilemma. You cannot put a price tag in human terms on such a gift. Yes, a transplant procedure and follow-up is expensive, but relative to the lost productivity, the impact on the quality of life, and the cost of living with end-stage heart or renal disease, transplantation is, indeed, very cost effective.

Mr. BILIRAKIS. Dr. Neylan, forgive me, but if you could summarize.

Mr. NEYLAN. I will be happy to. And also, it may be the only hope, not just for improved survival but for a full and healthy life for these individuals and their families. Through better education and awareness campaigns, we can win this important battle together.

Thank you, Mr. Chairman.

[The prepared statement of John F. Neylan follows:]

PREPARED STATEMENT OF JOHN F. NEYLAN, PRESIDENT, AMERICAN SOCIETY OF
TRANSPLANTATION

Mr. Chairman and Members of the Subcommittee, thank you for the opportunity to present testimony on behalf of the American Society of Transplantation (AST).

I am John F. Neylan, M.D., Medical Director of Kidney Transplantation at Emory University and I am President of the American Society of Transplantation (AST). The AST, which has no governmental support, was established in 1982. Our membership, now over 1,400 members strong, is comprised of physicians, surgeons, and scientists actively engaged in the research and practice of transplantation medicine and immunobiology. As such, AST represents the majority of professionals in the field of transplantation in the United States.

Over the last 30 years, transplantation of solid organs has moved from experimental to accepted therapy, with over 20,000 performed in 1998 alone. The success of this procedure has improved greatly over the last few years with almost all solid organ recipients enjoying an 83-97% survival rate at one year. Much of this success can be attributed to research in immunosuppression that has been funded by previous federal appropriations. Our better understanding of the body's response to foreign proteins has led to countless other breakthroughs in all areas of medical science. However, this success has brought with it new challenges.

More and more individuals are agreeing to be placed on waiting lists for an organ transplant, and as a result the list has increased in size by 255 percent in the last ten years. It is unfortunate and absolutely unnecessary for those in need of a transplant to go without the "Gift-of-Life." This happens because the supply of available donors is far less than the demand.

I would like to focus my testimony on the most important issue facing the transplant community today, providing transplantable organs for patients in need. Even as we in the transplant community continue the deliberate and at times difficult process of determining the optimal means to allocate a precious though numerically inadequate resource, we must never forget the "crux" of the problem and the real solution... increasing organ donation.

During the next hour, four new names will join those 58,000 individuals in this country waiting for a solid organ transplant. And by the time I get home to Atlanta this evening, 10 individuals will have died because the wait for a transplant was just too long. It is unfortunate and absolutely unnecessary, but the sad fact is that we as a nation are not living up to our potential. Too many families are turning down the option of organ donation.

But, Mr. Chairman, with increased education and improved coordination among the public and private sectors, we can improve donation rates and thus make the gift-of-life a reality for thousands of Americans. The AST believes strongly that federal and state governments, providers, and the patient community need to establish a working compact directed at translating the extremely high public awareness of the "gift-of-life" into a pro-active national effort to increase organ donation. Only by working collectively as the transplant community, with all stakeholders involved, can we successfully address the issue of donation. In addition, the AST strongly supports Congressional reauthorization of the National Organ Transplant Act, which was last reauthorized in 1990, to enhance support for organ donation initiatives.

In my own state of Georgia, there are numerous examples of such good works. Many communities have rallied financial support for someone amongst them in need of a liver transplant. Through these efforts, socioeconomically disadvantaged patients have received the fruits of this life-saving but costly medical miracle. On another level, we have within our state a charitable organization entitled the Carlos and Marguerite Mason Fund which has provided millions of dollars for transplant research, patient support and also organ donation initiatives. An example of the latter is an ongoing minority outreach program which seeks through multiple interventions to enhance donation within the African-American community. And at the state level, Georgia has clearly demonstrated a real and tangible financial support for

organ donation by providing a discounted driver's license renewal fee to those who designate their personal support to the cause of organ donation.

Last year, the AST worked closely with Congressman Elijah Cummings to introduce and pass, in the House of Representatives, legislation (H.R. 2943), to increase the amount of leave time available to Federal employees serving as donors. In the past, a lack of leave time has served as a significant impediment and disincentive for individuals willing to share the gift-of-life. The legislation has been reintroduced in the 106th and strongly supported by our Society. AST believes that targeted initiatives such as Congressman Cummings legislation can collectively make a difference, especially those initiatives which support living donation. Indeed, programs that enhance living donation may be among the most immediate, most effective and least expensive activities available to our nation today.

As we all know, organ donation is the real answer to dealing with the dilemma of allocating and distributing an inadequate supply of organs. In addition to our own efforts, and those of the greater transplant community, the AST has consistently urged the Federal Government to continue to take on a greater leadership role in this most important component of the problem through increased research funding, public education and awareness campaigns, and through the implementation of the hospital participation in Medicare and Medicaid regulations requiring notification of potential donors to the organ procurement organizations (OPO).

A year and half ago, the Administration moved forward with a national organ and tissue donation initiative to encourage more families to discuss and understand their loved ones' wishes in regard to donation. Most recently, these activities have included a National Donor Day, and this week, a National Donor Recognition Ceremony to honor those individuals who have given the ultimate gift... the gift-of-life. These important initiatives serve to raise national awareness and educate the public regarding the importance and critical need of their participation in the organ donation process. Such activities are helpful in the reduction of family refusal, which is the number one cause of loss of potential donors today. As a result, the AST has advocated and strongly urged, through testimony before the House and Senate Appropriations Committees, that increased funding be provided to the Division of Transplantation, located in the Health Resources and Services Administration with additional funds for FY 2000. Such funding will help to insure the success of these and other programs federally initiated to enhance donor awareness and improve the public trust in the process.

We all know and understand that increasing our nation's supply of organs is the real answer to our current dilemma. You can't put a price tag in human terms of such a gift. Yes, a transplant procedure and follow-up care is expensive. But, relative to the lost productivity, the impact on quality of life, and the cost of living with end stage heart or renal disease, transplantation is very cost effective. Also, it may be the only hope not just for improved survival, but for a full and healthy life for many individuals and their families. Through better education and awareness campaigns, we can win this important battle.

Thank you.

Mr. BILIRAKIS. Thank you very much.
Dr. Metzger?

STATEMENT OF ROBERT A. METZGER

Mr. METZGER. Mr. Chairman, members of the subcommittee, my name is Robert Metzger and I am the Medical Director of both the Translife Organ Procurement Organization and the kidney transplant program at Florida Hospital Medical Center in Orlando, Florida. I also serve as the incoming medical advisor of the Association of Organ Procurement Organizations, or AOPO, the membership organization that represents all 62 organ procurement organizations in the Nation. I am also the Vice Chairman of the Council for Organ Availability at UNOS. I would like to thank the committee for providing this important forum on the national shortage of organs for transplantation.

In brief, as you have heard, our dilemma is that we simply do not have enough organs to satisfy the demand. While there will always be a need for allocating organs, reaching agreement on such

a plan would be much easier if we could expand the supply of available organs. It is here that I will focus my remarks today.

Five thousand potential recipients will die awaiting transplantation this year, although over the past decade the number of donor organs recovered has increased somewhat. The increases come about in three major ways.

First, there has been a steady increase in the number of donors coming from the older age groups, especially 65 and above. Unfortunately, these organs function less well.

Second, there are more living donors, especially from genetically unrelated spouses and friends. With reimbursement of personal expenses, I feel this pool could increase substantially.

Third, efficiency in organ procurement has increased with more solid organs procured per donor. Developments in utilizing non-heartbeating donors and split livers and lungs offers some promise for expanding this procurement efficiency.

Important initiatives have been taken to enhance OPO effectiveness. The range is broad, including the establishment of continued quality improvement teams, the conduct of general public awareness campaigns, targeted community outreach to ethnic and racial populations, school education programs, and special emphasis on donor families.

Increasing donation is not an easy task. The challenge is compounded by the fact that we have poor knowledge of how effective we are in recovering organs. The primary reason for this is that we do not have a good measurement of OPO efficiency and the HCFA standards currently used to measure this are woefully inadequate. Unless we develop an accurate knowledge of the actual donor potential in our region, it remains impossible to assess our effectiveness.

Fortunately, new methodologies spearheaded by AOPO's death record review study is addressing this issue. More than half of the Nation's OPOs are participating in this study and the preliminary results indicate that only about 40 percent of potential donors actually become donors. Of the remainder, most were either not identified or referred as potential donors or the family declined to consent to donation. Yet approximately 75 percent of Americans surveyed in public opinion polls say that they would support organ donation for themselves. A window of opportunity clearly exists.

Over the past 15 years, a number of State and voluntary efforts have resulted in increased hospital referral rates to the OPO community. Based on this success, HCFA promulgated new Medicare hospital conditions of participation last August that mandate all in-hospital deaths be referred in a timely way to the local OPO so that a determination can be made if the patient is a potential organ donor. The regulations also specify that only expert requestors, that is, OPO staff or hospital staff specifically trained to request organ and tissue donation in an appropriate manner, are permitted to approach families.

Although it is too early to judge the effectiveness of this rule, it does address the two major deficiencies noted above and we are seeing significant increases in referral calls made to many local OPOs as well as improved hospital cooperation.

In the context of reviewing barriers to organ donation, a critical issue that has a clear impact on the effort to increase organ supply is the turmoil created by the current practice of OPO recertification and performance evaluation. The current OPO certification process, which occurs every 2 years, has perhaps unintendedly created the strange result of introducing major distractions and, indeed, disruptions to the mission of OPOs to increase the supply of organs. Unlike hospitals, for example, the certification period for OPOs is much shorter, the criteria for evaluation do not measure OPO performance or capability, is without due process for resolving deficiencies, contains no corrective action clause, and OPOs found deficient are directed to close their doors. Although the current measures have been in use by both the government and industry, there is widespread agreement that these measures are not meaningful for judging or improving performance.

With the new conditions of participation in place and giving the compelling results of recent empirical work, the time is ripe for placing a moratorium on the current certification process and supporting a collaborative industry-government examination of alternative OPO performance measures.

In closing, I do want to commend the committee again for convening this brief examination today on organ supply. I would encourage, furthermore, that consideration be given to reauthorization of the National Organ and Transplantation Act and the provision of a broader forum to revisit these issues.

Thank you again for this opportunity to testify today.

[The prepared statement of Robert A. Metzger follows:]

PREPARED STATEMENT OF ROBERT METZGER, MEDICAL DIRECTOR, TRANS LIFE ORGAN
PROCUREMENT ORGANIZATION

My name is Robert Metzger and I am the Medical Director of the TransLife Organ Procurement Organization, at Florida Hospital Medical Center in Orlando, Florida, and also am Medical Director of the TransLife Transplant Program. I am boarded in the Internal Medicine subspecialty of Nephrology and have had a career covering practice, education, research, and administrative aspects of medicine. I also serve as the Medical Advisor-Elect of the Association of Organ Procurement Organizations (AOPO), the membership organization that represents all 62 organ procurement organizations (OPO) in the nation, with its collective goal of maximizing the number and quality of organs (and tissues) available for transplant. In addition, I am currently the Co-Chair of the Council for Organ Availability of the United Network for Organ Sharing (UNOS).

Today, I am here in my Medical Director capacity with the TransLife Organ Procurement Organization and Transplant Program, but am prepared to respond to questions regarding the focus of both AOPO and the UNOS Council for Organ Availability. I would like to thank the Committee for providing this important forum to address the matter of our continuing national shortage of organs for transplantation, and the opportunity given me to comment on key issues regarding the inadequate supply of organs and the role of OPOs.

Organ transplantation is a unique part of American medicine. While there are many areas in which medical care is rationed implicitly, transplantation is the only one where we must do so explicitly. We simply do not have enough organs to satisfy the demand, so we must develop complicated systems of allocation. While there will always be a need for some system of establishing priority for a scarce resource, reaching agreement on such a plan would be much easier if we could expand the supply of available organs. It is here that I will focus my remarks today.

At the outset, I would like to briefly comment on what an organ procurement organization (OPO) is, and how it is central to the general topic of today's proceeding. In brief, OPOs are organizations that are the captains of the supply side of the industry. They are the experts when it comes to talking about supply availability.

In coordinating activities relating to organ procurement in a designated service area, OPOs are the professionals who evaluate potential donors, discuss donation with family members, and arrange for the surgical removal of donated organs. It is the OPOs who are the experts responsible for preserving the organs and making arrangements for their distribution according to national organ sharing policies. These organizations, furthermore, provide information and education to medical professionals and the general public to encourage organ and tissue donation, and increase the availability of organs for transplantation. The OPOs are federally certified by the Health Care Financing Administration (HCFA). The new web page of AOPO (<http://www.aopo.org>) provides a complete listing of the OPOs in the nation.

The service population of OPOs varies across the nation from a low of about one million to a high of nearly twelve million people. TransLife has a service population of 2.4 million people covering ten counties in east Central Florida.

As you know, our continuing national crisis is real. Of the more than 60,000 patients currently waiting for an organ transplant in this country, about 20,000 will receive a transplant, 35,000 will continue waiting while the disease progresses, and 5,000 will die. It has been estimated that an increase in organs of around 18,000 to 20,000 would be required to conform demand (as measured by the addition of new patients to the waiting lists, deaths, and removal from the lists due to advanced disease) with supply (as measured by the number of transplants performed.)

Over the past decade, the number of donors recovered in the nation has increased somewhat. At TransLife, 78 donors were recovered this past year, compared to 74 in 1997 and 69 in 1996. Although that corresponds to over 32 donors per million population and ranks near the top by current HCFA standards for OPOs, you will see shortly that we don't really know what that standard means. The national increase to date has come about in three major ways. First, most of the change in the number of organ donors has come from the older age groups, especially 65 and above. Criteria for accepting cadaver donors have begun to be liberalized and expanded. In addition to increasing age, larger numbers of donors are occurring with diabetes, hypertension, some infections, and other conditions. Unfortunately, there is a trade off in poorer graft function in these expanded criteria donors.

Second, there are more living donors. There were over 4100 living-donor transplants in the United States in 1998 up from 3905 in 1997 and 3690 in 1996. Of note is the fact that from 1996 to 1998, the percentage of spouses and friends who were emotionally, as opposed to genetically, related donors increased from 3.9% to 12.5%, significantly contributing to the overall improvement. Third party living donors, neither genetically or emotionally related, but altruistically motivated, are being considered in some programs. I feel living donors would be even more plentiful if Medicare and other third party payers would reimburse these individuals for their out of pocket expenses and the lost wages associated with this heroic act.

Third, efficiency in organ procurement has increased, with more solid organs procured (and transplanted) per donor. Although this donor-transplant ratio has risen substantially since the late 1980's, much of the improvement through 1996 was recorded in the earlier part of the period.

Other developments such as the revisited interest in non-heart beating donors and medical advances in split livers and lungs are among important areas that show promise for expanding the organ pool. Non-heart beating donors, donors in whom the family requests that life support be withdrawn but may not yet be clinically brain dead, could add substantially to the pool of kidney and liver organs. However the procurement of organs from these donors is labor intensive and yet to be fully embraced by the organ procurement and transplant community. The Institute of Medicine's ongoing evaluation of this issue is awaited. Split liver and lung techniques may also increase in the future in both living and cadaver donors and I would be happy to comment on these developments.

Across the organ procurement community, a number of examples can be cited of important initiatives that have been taken to enhance OPO effectiveness. For example, TransLife developed "Tiger Teams" at three of our major donor hospitals. These are organizations of health care professionals who are committed to supporting and promoting organ donation. The multidisciplinary teams include representatives from Nursing, Hospital Administration, Clergy, the Medical Examiner's office and Social Services. The teams meet on a monthly basis to discuss donor activity and consent rates; conduct case reviews and assist the OPO in planning education. They keep donation at the forefront of their respective facilities. LifeNet, based in Virginia Beach, Virginia, enlisted hospital administrators from every hospital in its service area to send representatives to form an OPO liaison council that would help to develop and implement new strategies. This LifeNet Liaison Council contributed to improved hospital relations leading to the successful initiation of voluntary routine referral of potential organ donors in all their facilities.

The range of successful initiatives among OPOs is broad and includes the following: 1) establishment of continuous quality improvement teams, 2) the conduct of general public awareness campaigns, 3) targeted community outreach to ethnic and racial populations, 4) school education programs and curriculum development, 5) special emphases on donor families and bereavement counseling services, and 6) other focused programs to work collaboratively with local hospitals.

Increasing donation is not an easy task. A lot of smart, dedicated, hard-working professionals in the nation's 62 OPOs, and many others, have spent much time, energy and money tackling this problem. The challenge before us is compounded by the fact that we really don't know whether we are being more or less efficient in our recovery of organs. The reason is that we don't have a good understanding of the underlying potential for brain-dead, heart-beating (that is, "standard") organ donors, and how it is changing from year to year.

As we struggle to eradicate the organ shortage, two of the most limiting factors in organ donation come into focus: (1) failure to determine which patients are potential organ donors and the lack of referral of these patients to OPOs; and (2) the refusal of patients' families to consent to donation.

Without knowing the denominator in the organ procurement equation, it is impossible to tell if we are increasing the percentage of potential donors converted into actual donors. It may be, as many suspect, that the donor pool is actually shrinking through a decline in deaths from traumatic causes—motor vehicle accidents, homicides, suicides, etc. This traditionally has been a major source of organ donors. If this is true, then the increase in donors may be more significant than it might otherwise appear.

The need to understand the size and nature of the potential organ donor pool, and how it varies from region to region, was the impetus several years ago for AOPO to begin a detailed examination of this issue. More than half of the nation's OPOs now are participating in this study, which employs a standard methodology to retrospectively review hospital medical records. From these data, the number and distribution of potential donors can be determined, and the efficiency in converting potential into actual donors can be measured.

The UNOS Council for Organ Availability, which I Co-Chair, is very interested in monitoring the progress of this study as it continues in to its second phase. Indeed, our Council is charged with developing information on best practices among the more effective OPOs in the nation. The initial challenge for us, ironically, is to identify the more effective OPOs. Standard measures used to date for assessing OPO performance, are clearly inadequate and can be quite misleading, a point I will return to later. The availability of alternative measures, such as looking at OPO performance in the context of potential donors, offers great promise in giving us a better profile for our charge.

Preliminary results of the AOPO study indicate that only about 40 percent of the potential donors actually became donors. Of those who were not donors, most were identified as potential donors, but the family declined to consent; and in some cases the family was never asked. Yet over 75 percent of Americans surveyed in public opinion polls say that they would support organ donation for themselves. Therefore if we can assure 100 percent identification of potential donors in a timely way, and we can have a trained, expert requester approaching families at the right time, with the right information, we ought to be able to move the donor conversion rate from 40 percent to something much higher.

A sobering statistic underlying concerns with the referral of potential organ donors is the estimate that 27 percent of the medically suitable organ donors in the US are never recognized as potential donors. As highlighted in the current issue of *Critical Care Nurse*, which provides special attention to clinical dimensions of organ donation, "reasons why hospital staff do not recognize which patients are potential organ donors and refer these patients to the OPO include lack of knowledge about the criteria for organ donation, reluctance to spend the time to get the OPO involved, and uncertainty about how to initiate the donor referral process."

Over the past fifteen years, a number of efforts have been undertaken in different parts of the country to increase hospital referral rates to the OPO community. In recent years, the more prominent legislative efforts have taken the form of "routine notification" legislation passed in a number of States, which required that all deaths or deaths that are imminent within a hospital be referred to the Medicare-certified OPO. Based largely on the experiences in these States (Pennsylvania being the most notable), HCFA promulgated the new Medicare Hospital Conditions of Participation last August. These regulations, which are only now being implemented, mandate that all in hospital deaths be referred in a timely way to the local OPO so that a determination can be made if a patient is a potential organ donor. The regulations also specify that only expert requesters—that is, OPO staff or hospital staff specifi-

cally trained to request organ and tissue donation—are permitted to approach families.

There have been early implementation difficulties. These include the absence of an age cut off for death referral calls, questions regarding how and whom to train on the hospital staff, especially physicians, problems occasioned by some hospitals asking patients about organ donation upon admission, and referrals to and conflicts with and among tissue banks. Overall, however, the regulation has made important inroads towards improving the percentage of potential donors, improving the timeliness of referrals to the OPO, and improving the effectiveness of the consent process.

Already we are seeing significant increases in referral calls made to local OPOs, unless the OPOs and hospitals are in settings where either legislated or voluntary routine referral was in place before the federal rules were promulgated. In some instances, calls have increased from 50 per month to nearly 2,000. Given the fact that there currently is no age limit on the referral calls, it is clear that most of these calls do not involve potential donors for solid organ recovery. The largest increases are occurring in tissue donor referrals. Nonetheless, earlier State experiences with routine referral laws have translated into increases in organ donation. When fully implemented next August and in subsequent years, we expect that the federal regulations will produce similar results.

Failure to obtain request for consent represents an equally important limiting factor to achieve greater success in organ availability. Estimates suggest that around one-third of the medically suitable organ donors in the US do not donate because the family of the potential donor refuses to consent to donation.

Research regarding the consent process has indicated critical ingredients for dramatically increasing success in obtaining consent. First, it is important to de-couple discussions about brain death and discussions about organ donation. Second, private discussions are best. And, third, OPO participation with hospital staff is advantageous. Although these methods are not uniformly understood or practiced, the recently promulgated Medicare Conditions of Participation do strengthen these dimensions by specifically stating that families must be approached in a sensitive and caring fashion by OPO staff members or by designated requesters who complete OPO training requirements. Early returns on implementation of these regulations, furthermore, do suggest that the hospital and organ procurement industries are moving ahead collaboratively to make this work.

In the context of reviewing barriers to organ donation, a critical issue that has a clear impact on the effort to increase organ supply is the turmoil created by the current practice of OPO recertification and performance evaluation.

The current OPO certification process, which occurs every two years, has perhaps unintendedly created the strange result of introducing major distractions and indeed disruptions to the mission of OPOs to increase the supply of organs. Unlike hospitals, for example, the certification period for OPOs is much shorter, the criteria for evaluation do not measure OPO performance or capability, a clearly defined due process component for resolving complaints does not exist, no corrective action plans are included, and OPOs that are found deficient by the current measures simply are directed to close their doors.

The OPO certification process sets an arbitrary population-based performance standard for certification of OPOs based on donors per million of population (DPMP). It sets a standard for acceptable performance based on five criteria: donors recovered per million, kidneys recovered per million, kidneys transplanted per million, extra-renal organs recovered per million, and extra-renal organs transplanted per million. These current measures of performance do not adequately distinguish among OPOs and do not necessarily correlate with actual donor potential and OPO efficiency. A very effective OPO that is getting a high yield from potential donors may look terrible because they have a lot of AIDS, older people, minorities and other risk factors in the population. At the same time, a very ineffective OPO may look good because they have a population with a high proportion of potential donors.

Under current regulatory practice, OPOs are decertified if they fail to meet the 75th percentile of the national means on 4 of the 5 performance measures. Service areas are reassigned to another OPO whose performance is greater than the 75th percentile of the national mean. Therefore, it is a mathematical certainty that some of the OPOs must fail each cycle—no matter how much they individually improve.

From the perspective of OPOs, the process is like musical chairs. Every two years, you take two chairs away, with no real rhyme or reason. Unfortunately, worrying about the dance has often diverted enormous energy on the part of the OPO community from our primary mission of increasing organ supply. Particularly distressing is that this do or die approach, based on measures that offer no real stimulation to do a better job, may very well undermine the time and effort needed to enhance the positive objectives of the new Conditions of Participation.

A critical need exists to know the expected performance of OPOs based on their potential. It is hard to improve what you can't measure accurately.

Although the population-based measures have been in use by both the government and industry, it is important to note that there is widespread agreement that these measures are not meaningful for improving performance. In 1997, for example, the General Accounting Office issued a report concluding that the existing standards of performance are not valid measures for determining OPO performance and that a new system should be developed which takes into consideration each OPO's particular service area and the potential of that service area. Indeed, it is possible that efficient OPOs have been shut down based on these criteria with disruption of an effective donation process in areas served by what seems to be poorly performing OPOs.

In recent months, some important new data has been developed, shared with HHS and GAO officials, which has significant policy implications for considering alternative OPO performance measures. Specifically, APOPO has made significant progress on its major death record review study, which includes an unprecedented amount of quality data collected on donor potential. The study recently produced preliminary results from its major death record review, which indicates poor correlation between OPO potential and the current population standards. A Harvard School of Public health study recently reported similar results from a mathematical model for calculating organ donor potential in OPO territories as did a report from the United States Renal Data System (USRDS) published recently in the journal Transplantation. Members of the Committee might find presentations regarding these efforts to be of particular assistance in additional deliberations regarding this area.

In order to stabilize organ procurement and focus on improving our performance in increasing the supply, we need the following:

- An immediate moratorium to the current recertification process and the use of the current performance measurements. HCFA can do this administratively by extending the certification process from 2 to 4 years as they were directed in the Balanced Budget Act of 1997. The moratorium should last until there is a new process in place.
- Support for a collaborative effort among HCFA, IOM, GAO, and the Industry to develop better measures of OPO performance—measures that can determine potential and will focus OPOs effectively on increasing the supply of organs.
- Negotiated rule making with HCFA and the Industry to design a new recertification and performance measurement process.
- The new process should include a longer time between recertifications; due process for plans that fail; an opportunity for a corrective action plan.

In closing, I do want to commend the Committee again for convening this brief examination today of the issues around increasing the nation's supply of organs. Given the urgency of these matters, I would encourage, furthermore, that consideration is given by the Committee this session to reauthorize the National Organ and Transplantation Act (NOTA), amended to include:

- Financial reimbursement for lost wages and personal expenses for all living donors.
- Research funding to further explore and define factors resulting in improved consent for donation.
- Further emphasis to the general public that organ donation saves lives.

Thank you again for the opportunity to testify today. I will be happy to answer any questions.

Mr. BILIRAKIS. Thank you so much, Dr. Metzger.
Dr. Higgins?

STATEMENT OF ROBERT S.D. HIGGINS

Mr. HIGGINS. Thank you. Mr. Chairman and members of the committee, thank you for this opportunity to submit testimony on increasing organ supply for organ transplantation. My name is Robert Higgins. I am a surgeon and physician and director of the heart and lung transplant program at Henry Ford Hospital in Detroit, Michigan. I serve as the Region X, which includes Michigan, Indiana, and Ohio, thoracic organ transplant committee representative for the United Network for Organ Sharing, or UNOS.

I am here today representing Henry Ford Hospital and the Patient Access to Transplantation Coalition, or PAT. Formed in June 1998, the Patient Access to Transplantation Coalition is an independent and informal coalition of 31 transplant centers and other medical institutions which provide local access to nationally recognized excellence in transplant care. Although our membership is diverse, one aspect of our mission is clear. We work to ensure that more organs are available to more patients. The PAT Coalition believes that, in reality, donation occurs locally and not nationally and involves donor families, physicians, hospitals, and organ procurement organizations all working closely together within a local setting.

As physicians, we are thrilled with the advancements that allow us to help more and more patients. We are also deeply concerned that the supply of organs limits this field of life-giving therapy. We applaud you, Mr. Chairman, for scheduling this crucial hearing to discuss ways we can work together to increase organ donation. In the next few minutes, I would like to share with you main strategies which we have employed to increase the availability of organs. These include public awareness and education to encourage families and individuals to consider donation, improving ways to work with patients and families at the decision point when organ donation is offered, and increasing the supply through techniques such as split liver procedures that benefit two recipients instead of one and increasing the use of living donors.

In the State of Michigan, there are eight transplant centers, with the Henry Ford Hospital and the University of Michigan Health System accounting for 40 percent of the organ transplants performed in the State. The Transplantation Society of Michigan serves as the federally designated organ procurement agency for the entire State and allocates organs for each transplant center.

Henry Ford Hospital is serving a population in southeast Michigan of over 800,000 aligned patients, including large Medicare, Medicaid, and managed care populations. Over the past 30 years, more than 1,700 patients have received an organ transplant at Henry Ford Hospital, giving patients a second lease on life. Southeast Michigan is home to a large African American population, which experiences a higher than average incidence of hypertension, diabetes, chronic kidney disease, and other chronic illnesses which often leads to the need for transplantation services.

Our transplant program is located in the city of Detroit, where approximately 75 percent of residents are African American. The recent development of transplant centers in urban centers, such as the Henry Ford Health System, provides local access for patients from all walks of life. Without a geographically accessible program in the vicinity, costs to patients' families and those with limited financial resources may be prohibitive.

Nationwide, over 62,000 patients await life-saving or life-enhancing organ transplants. In the kidney failure population, as I am sure you will hear, close to 40 percent of those are African American. Transplant programs at institutions such as the Henry Ford Hospital serve predominately urban populations and provide critical access to transplant programs in the region. Among the pa-

tients served by our hospital, more than 40 percent are covered either by Medicare or Medicaid.

Historically, African Americans have donated less frequently than others. A number of reasons have been identified, including a lack of information about transplantation, religious beliefs, fear of premature death, and mistrust of the medical community. The Henry Ford Health System has developed critical partnerships with a number of organizations, such as the Patient Access to Transplantation Coalition, to address many of these issues.

We have also developed partnerships with the National Minority Organ Tissue Transplant Education Program, or MOTTEP, which is designed to educate minorities on the facts about organ and tissue transplantation and to increase the number of persons who actually become donors. It delivers a culturally sensitive message by ethnically similar messengers within minority communities. MOTTEP has been effective in advancing the goal of improving organ donation rates in our African American community.

Last year, the PAT Coalition worked actively with the Appropriations Committee to achieve substantially increased Federal dollars directed toward organ donation. We commend Congress for appropriating these funds. We also take great pride in the leadership of the Michigan delegation, who in 1996 supported a campaign to increase organ donation rates in the United States through legislation that allowed information on organ donation to be included in IRS refunds.

In the State of Michigan, the Secretary of State, Candace Miller, has recently implemented an organ donor registry through legislation approved by the Michigan legislature and this has increased donors by 140 percent since 6 months after its implementation. The law requires the Secretary of State to provide ID and driver's license applicants information about Michigan's organ procurement agency as well as explanations of what an anatomic gift is. Since the Michigan organ donor registry started, approximately 2,000 names have been added each week to the list of potential donors. The number of registered potential organ donors has increased from 16,000 in July 1998 to approximately 40,000 names today.

Henry Ford Hospital has also embraced additional strategies to alleviate the organ shortage. Living related kidney donation is a very powerful tool to increase the number of organ donors. In 1997, an African American man in his mid-40's needed a kidney transplant. None of his family members were found to be a suitable match. In the absence of an available cadaveric donor, an alternative means was needed. A close friend and coworker, who happened to be white, offered to be tested. As it turned out, the friend was a perfect match and our first cross-racial living organ donation surgery took place. Both patients recovered well and continued their friendship. Our community rallied behind the cross-racial living organ donation and celebrated both the medical and community triumph. Living related organ donations now comprise approximately 50 percent of the Henry Ford Hospital kidney transplant patients.

Another innovative approach to alleviate the shortage is the split liver transplant procedure, where two recipients receive a donor organ when clinically appropriate. We performed our first split

liver transplant for two female patients in 1997. These donations can be particularly important to children, who account for approximately 10 percent of those waiting for a liver transplant. Many physicians feel the split liver procedure can be an effective strategy to address the organ donor shortage in pediatric populations, and as more transplant centers become comfortable with this procedure nationwide, it may have a significant impact.

Congress has a unique opportunity to provide legislative leadership in refocusing the national organ debate on donation and the PAT Coalition urges the Commerce Committee to lead on this issue by supporting legislation which gives the public genuine motivation and incentives to be aware and willing to become organ donors. Specific areas which may be considered include creating travel and subsistence incentives for those who want to donate in living related transplant procedures, creating a national registry for organ donors, and continuing expansion of the new HRSA organ donation extramural research program.

In closing, I applaud the involvement of Congress in initiatives to put patients and families first and to increase the organ supply for transplantation. As we move forward with new procedures and technology, we must also continue our efforts to raise public awareness and work with our communities to donate the precious scarce resource of organs. Thank you for your efforts.

[The prepared statement of Robert S.D. Higgins follows:]

PREPARED STATEMENT OF ROBERT S.D. HIGGINS, DIRECTOR OF THORACIC ORGAN TRANSPLANTATION, HENRY FORD HOSPITAL, ON BEHALF OF THE PATIENT ACCESS TO TRANSPLANTATION COALITION

Mr. Chairman and Members of the Committee, thank you for this opportunity to submit testimony on increasing organ supply for organ transplantation. My name is Robert Higgins. I am a physician and Director of Thoracic Organ Transplantation at Henry Ford Hospital in Detroit, Michigan. I serve as the Region 10 (Michigan, Indiana and Ohio) Thoracic Organ Transplant Committee Representative for the United Network for Organ Sharing (UNOS). I am here today representing Henry Ford Hospital and the Patient Access to Transplantation (PAT) Coalition.

As we enter into a new millennium, our nation can point with pride to many miraculous medical technological breakthroughs, including remarkable advances in transplantation services. Improvements in drugs, practices and technology in the transplant field have enabled doctors to perform more life saving procedures, with better results than ever before. The organ shortage is really a hallmark of this success. With improvements in transplantation science and technology, the number of patients who can benefit has increased dramatically, outstripping the supply of organs. This is the real story. As physicians engaged with our patients in one of the most sensitive areas of medicine, we are thrilled with the advancements that allow us to help more and more patients. We are also deeply concerned that the supply of organs limits this field of life giving therapy.

We see our patients as mothers, fathers and children in the context of a family and community that benefits from their ability to live and carry out their responsibilities. We are able to provide stabilization care and hold out the promise of a continued active life through transplantation. To many of us, the only barrier appears to be lack of available organs. Waiting times do vary across regions of the nation and unfortunately, as many as 13 people die in our nation every day while waiting for an organ transplant because of the shortage of organs. We applaud you, Mr. Chairman, for scheduling this crucial hearing to discuss ways we can work together to increase organ donation.

What I will cover with you are the main strategies we employ for increasing the availability of organs. These are:

- Public awareness and education to encourage families and individuals to consider donating healthy organs in the event of imminent death;
- Improving ways to work with patients and families at the decision point where donation is to be considered;

- New procedures and technology that improves the success rate for transplantation services. This includes better selection criteria of patients most likely to benefit, improved techniques for maintaining the viability of the donated organ until it can be placed, and improvements in drugs and other therapies to reduce rejection rates; and
- Increasing the supply through techniques such as split liver procedures that benefit two receiving patients instead of just one, and the increased use of living donors.

It is important to keep in mind, however, that the number of organs needed to fill demand will always be a moving target. This is because technology also helps to continuously expand the number of patients that can benefit from transplantation.

Public Awareness and Public Education

More than 62,000 patients currently await organ transplants. Last year the PAT Coalition worked actively with the Appropriations Committees to achieve substantially increased federal dollars directed at organ donation. We commend Congress for appropriating \$5.9 million above the Administration's budget request. We also take great pride in the leadership of the Michigan delegation who in 1996 supported a campaign to increase organ donation rates in the U.S. through legislation that allowed information on organ donation to be included with IRS refunds. We appreciate this and other wonderful efforts of Congress, such as this hearing, to focus public attention and create awareness about the need for organ donation.

In Michigan, Secretary of State Candice Miller recently announced that registry legislation which the Michigan Legislature passed last year already has increased the number of organ donors by about 140% since the program began operating six months ago.

The Michigan law requires the Secretary of State to provide ID and driver's license applicants information about Michigan's organ procurement agency, as well as an explanation of what an anatomical gift is. The law also established a registry of names of persons willing to be an organ and tissue donor. Licenses and ID cards now contain a statement that the licensee is an organ and tissue donor, which can be honored by hospitals, physicians and family.

Since the Michigan organ donor registry started, approximately 2,000 names have been added each week to the list of potential donors. The number of registered potential organ donors has increased from 16,387 in July 1998 to approximately 40,000 names today.

Historically, African Americans have donated less frequently than others. A number of reasons have been identified, including a lack of information about transplantation, religious beliefs, fear of premature death, and mistrust of the medical community. The National Minority Organ Tissue Transplant Education Program (MOTTEP) is designed to educate minorities on the facts about organ and tissue transplantation and to increase the number of persons who actually become donors. We in Michigan perceive that it delivers a culturally sensitive message by ethnically similar messengers within the minority communities. MOTTEP has been extremely effective in advancing the goal of improving donation rates in our African American community. The Transplantation Society of Michigan and Henry Ford Hospital have been partners with MOTTEP since its arrival in Detroit in 1995 and have provided administrative and professional guidance to this very important program.

Working with Families and Patients

Under a voluntary system, such as we have in the U.S., permission of the donor patient and/or family is required. For the most part, the voluntary system relies on hospitals and doctors to work with families to get the necessary permission. One of our strongest tools in this process is helping the giving family to understand the good that will come from the organ donation.

Let me walk you through the process of asking a family for an organ donation from their loved one. Generally, the injured or sick patient who arrives at the hospital was fine before the admission, and families are in shock at the life-threatening condition. The patient frequently has suffered a catastrophic brain injury from a stroke, aneurysm, care accident, gunshot, and other traumatic event. A social worker or other family support person is contacted to work with the family. Our LifeShare coordinator will assist by calling other family members, making sure the family understands what is happening with their loved one, and ensuring that everyone understands what the physicians and nurses have explained about the medical condition of the patient.

If the patient fails to respond to treatment and has been declared brain dead by two physicians, our LifeShare coordinator consoles the family, and asks if organ do-

nation had ever been discussed. The answer is usually, "No." We explain that this could be an opportunity to give life to someone else who is very sick.

Families will ask two main questions about donating: "Where will the organ go?" and "Who is the recipient—can we meet him/her?" We find that our families are reassured about the organ donation process when they are told organs are distributed locally first, then regionally, and then nationwide if a local match is not found. Families also like to know who the recipient is. This is often done through an anonymous letter writing process. Since there is great interest in meeting the organ recipient, this can be arranged if the families are locally based. This process has the effect of bringing closure to the grieving family and offering some consolation for their loss. It is a good process and reinforces deep human values for both the donor and the receiving patient.

Living Donors

Henry Ford Hospital has embraced additional strategies to help alleviate the organ shortage. Living related kidney donation is a very powerful tool to increase the number of organ donors available. I would like to share with you one case in particular at our institution. In 1997, an African American man in his mid 40's needed a kidney transplant. None of his family members were found to be a suitable match for his blood type and tissue type. In the absence of an available cadaveric donor, an alternative means was needed. A close friend and co-worker at General Motors who happened to be white, offered to be tested. As it turned out, the friend was a perfect match and our first cross racial living organ donation surgery took place. Both patients recovered well and continue their friendship. Our community rallied behind this cross racial living organ donation, and celebrated both the medical and community triumph. Living related organ donations now comprise approximately 50% of our Henry Ford Hospital kidney transplant patients.

Split Liver Transplants

Another innovative approach to alleviating the organ donor shortage is to split a single liver between two recipients when clinically appropriate. In 1997, we performed our first split liver transplant for two female patients who received the gift of life from a single donor. Split liver donations can be particularly important for children, who account for approximately 10% of those waiting for a liver transplant. Split liver procedures often involve one adult and one child because the smaller liver lobe is suitable for pediatric patients. The procedure has to be done by surgery teams that can handle both patients at the same time. Many physicians feel that the split liver procedure can be an effective strategy to address organ shortage for pediatric populations. As more transplant centers nationwide become comfortable with this technically challenging procedure, it may have a significant impact on alleviating the overall organ shortage.

Michigan Perspective

In the state of Michigan there are eight transplant centers, with Henry Ford Hospital and the University of Michigan Health System accounting for 40% of the organ transplants performed in the state. The Transplantation Society of Michigan serves as the federally designated organ procurement organization (OPO) for the entire State and is authorized to allocate organs among transplant centers in Michigan and qualified transplant centers nationwide under the Organ Procurement Transplantation Network (OPTN).

Henry Ford Hospital serves a population in southeast Michigan of more than 800,000 aligned patients, including large Medicare, Medicaid and managed care populations. Our transplant program began with corneal transplants in the 1960s. In 1968, the hospital's first kidney transplant was performed. Since then, our multi-organ transplant program has grown to include heart, liver, lungs, pancreas, kidney, autologous and allogeneic bone marrow transplantation. In 1998, 139 organ transplantations were performed at Henry Ford Hospital. Over the last 30 years, more than 1,700 patients have received an organ transplant at Henry Ford Hospital, giving patients a second lease on life.

Southeast Michigan is home to a large African American population which experiences a higher than average incidence of hypertension, diabetes, chronic kidney disease and other chronic illnesses which often leads to the need for transplantation services. Our transplant program is located in the City of Detroit, where approximately 75% of residents are African American.

The relatively recent development of transplant centers in urban centers across this country is an important improvement in our Health Care System, because it provides local access for patients from all walks of life. Without a geographically accessible program in the vicinity, costs to patients, families and those with limited financial resources can be prohibitive.

Nationwide, over 62,000 patients await life saving or life enhancing organ transplants. In the kidney failure population, close to 40% of those patients are African American. Transplant programs at institutions such as Henry Ford Hospital, which serve predominately urban populations, provide critical access to transplant programs in the region. Among the patients served by Henry Ford Hospital, more than 40% are covered by Medicare and Medicaid. Over 25% of the population we serve earns an economic income less than 100% of the Federal Poverty Level.

Formed in June 1988, the Patient Access to Transplantation (PAT) Coalition is an independent and informal coalition of transplant centers and other medical institutions which provide local access to nationally-recognized excellence in patient care. The PAT Coalition membership today consists of 31 transplant centers of varied size located in 21 states nationwide. Although our membership is diverse, one aspect of our mission is clear: ensuring that more organs are available to more patients.

The PAT Coalition believes that, in reality, donation occurs locally, not nationally, and involves donor families, physicians, hospitals and organ procurement organizations, all working closely together within a local setting.

The PAT Coalition and other private sector national organizations recognize that the establishment of transplant programs serving local, state, and regional areas has resulted in a marked increase in the total number of annual transplants in the United States, and firmly believes that the presence of a transplant program in a community or state provides a context and a focus for efforts to increase organ donation. Indeed, if centers are no longer able to operate in urban communities across this great nation, their transplant teams will no longer be available to recover organs in the surrounding area, further hurting donation efforts.

Congress has a unique opportunity to provide legislative leadership in refocusing the national organ debate on donation, and the PAT Coalition urges the Commerce Committee to lead on this issue by supporting legislation which gives the public genuine motivation and incentives to be aware and willing to become organ donors. Specific areas that should be considered in legislation include: creating travel and subsistence incentives for those who want to donate or receive organs, creating a national registry of organ donors, and continued expansion of the new HRSA organ donation extramural research program. Donation represents the arena in which all transplant interests can unite and work together.

In closing, I applaud the involvement of Congress in initiatives to put patients and families first and increase the organ supply for transplantation. Until we are personally touched by a tragic circumstance that revolves around organ transplantation, we cannot fully appreciate the value to our community of donors who give a second chance at life to so many sick individuals. As we move forward with new procedures and technology, so must we also continue our efforts to raise public awareness and work with our communities to donate the precious, scarce resource of organs. Thank you for your efforts.

Mr. BILIRAKIS. Thank you so much, Dr. Higgins.
Dr. Miller?

STATEMENT OF JOSHUA MILLER

Mr. MILLER. Representative Bilirakis and members of the committee, thank you very much for the opportunity to testify today. I am Dr. Joshua Miller, Professor of Surgery, Microbiology, Immunology, and Pathology and Chief of the Division of Kidney and Pancreas Transplantation at the University of Miami, Miami, Florida, in Jackson Memorial Hospital. I happen to be Cynthia Guillemin's transplant surgeon, but I have to admit that her last statement was not in the prepared thing that I read, so you will have to pardon that.

I am appearing today as the President this year of the American Society of Transplant Surgeons, the ASTS, which is the leadership organization of surgeons, physicians, and scientists who during the past 25 years of our existence have pioneered and continue to advance the frontiers of life-sustaining organ transplantation. Our Society has taken the field from experimental trials to highly developed treatment modalities that increasingly offer thousands of men, women, and children a new chance at an ever longer and

healthier life. ASTS members have the responsibility for directing clinical and research transplantation programs at America's major medical centers.

As part of this responsibility, we helped forge the National Organ Transplant Act into law in partnership with the U.S. Congress over 15 years ago. We conceived of an organ procurement and distribution network. And in partnership with the Health Care Finance Administration of the Department of Health and Human Services, helped organize it and put it into action during the same period.

Because of the explosive success of organ transplantation in the latter half of the 20th century—you have heard the numbers. There are 62,000 patients with end-stage failure of hearts, livers, lungs, pancreases, kidneys awaiting life-saving transplants this year, and probably fewer than 5,000 cadaver organ donors will provide us with only about 18,000 organs that can be used. Even with approximately 3,000 organs from living donors, the total number available does not begin to keep pace with the growing demand, so unless more organs become practically available for transplantation in the near future, the number waiting will forseeably pass 100,000.

How can we improve organ availability? Members of the ASTS are continuously working in the trenches with our patients and also in investigational laboratories seeking, one, innovative methods of improving the availability and quality of organs for transplantation; two, ways to more successfully preserve transplantable organs outside the human body; three, safer and medically acceptable ways to transplant from living donors kidneys, lungs, livers, and pancreatic segments; four, methods of safely splitting organs from cadaver organ donors; five, hastening the day when animal cells and organs will be available to replace their human counterparts using molecular technology; and six, working to advance our understanding of the human immune system.

We have extended our most recent initiative this year into operational practices and improving organ availability, and in a most important component, education of the American public, and these initiatives have taken two major directions.

Operationally, with our colleagues in the organ procurement organizations of America, we are already adapting novel approaches to improve the identification of organ donors in donor hospitals and in their physiologic maintenance in order to significantly increase organ availability, and this includes practical approaches now in operation in Spain and other practices in operation in Great Britain on donor maintenance. We did this after a week-long fact-finding tour in these countries last October and our working group then organized plans to set similar practices in place in demonstration regions in the United States.

We feel that there is the potential of actually doubling the number of heart transplants available to Americans with these particular practices. There also could be an improvement in overall organ donation in our country by at least 50 percent. That would enable us to provide a new chance at life to an additional 10,000 American men, women, and children each year, and I am pleased to provide two reports outlining progress in these initiatives for your detailed study.

The second major initiative is one of public education now 10 months into operation and it is called the First Family Pledge campaign. It was launched by the ASTS last May and has as its honorary co-chairs Reg and Maggie Green, who donated their 7-year-old son Nicholas's organs and tissues after he was murdered in Italy in 1994. The First Family Pledge campaign now has the support of all of the organizations involved in increasing organ and tissue donation in America, who several years ago, as you heard, formed the Coalition for Donation.

The whole concept of organ donation has not been well defined because the thoughts behind the process have not been clearly dissected and portrayed by us who know what we see in the trenches when consent for donation is requested and when organ transplants are performed. Organ donation and life-saving transplants are not merely individual acts. They require the participation and support of loved ones, the families close to the potential recipient who might die without the transplant, and the family of the potential cadaver organ donor, who must be included in this process in order that they understand the opportunity of saving lives of many after the tragic but inevitable death of their loved one. In fact, we could not proceed without family consent.

In any family's time of need, all family members obviously hope a life-saving organ will become available in time, and if we dare hope for this gift of life for our family, how can we do less than make a commitment in return, a family commitment to be there for them if the circumstances ever arise to save a life in other families, the lives of their loved ones through the reciprocal act of organ donation.

More than 250 Members of Congress publicly endorsed this initiative. This heartening surge in leadership support was demonstrated yesterday by the First Family Pledge Congress, in which many of the Members of Congress attended. I include an informational packet about this initiative for your perusal and would be happy to answer any questions about organ donation that I can. Thank you.

[The prepared statement of Joshua Miller follows:]

PREPARED STATEMENT OF JOSHUA MILLER, PRESIDENT, AMERICAN SOCIETY OF
TRANSPLANT SURGEONS

I appreciate the opportunity to testify at this hearing on Putting Patients First: Increasing the Organ Supply for Transplantation.

I am Dr. Joshua Miller, Professor of Surgery, Microbiology, Immunology and Pathology, and Chief of the Division of Kidney and Pancreas Transplantation, at the University of Miami School of Medicine in Miami, Florida.

I am appearing today as the President this year of the American Society of Transplant Surgeons (the ASTS) the leadership organization of Surgeons, Physicians, and Scientists who, during the past 25 years of our existence, have pioneered and continued to advance the frontiers of life-sustaining organ transplantation. Our Society has taken the field from experimental trials to highly developed treatment modalities that increasingly offer thousands of men, women, and children a new chance of an ever longer and healthier life. ASTS members have the responsibility for directing transplantation clinical and research programs at America's major medical centers.

As part of this responsibility we helped forge the National Organ Transplant Act into law in partnership with the United States Congress over 15 years ago. We conceived of an organ procurement and distribution network, and, in partnership with the Health Care Financing Administration of the Department of Health and Human Services, helped organize it and put it into action during the same period.

Because of the explosive success of organ transplantation in the latter half of the 20th century, there are now 62,000 patients with end-stage failure of hearts, livers, lungs, pancreases, and kidneys awaiting life-saving transplants. This year, fewer than 5,000 cadaver organ donors will provide us with only about 18,000 organs that can be used, applying current methodology.

Even with approximately 3,000 organs from living donors, the total number available does not begin to keep pace with growing demand. So, unless more organs become practically available for transplantation, the number waiting will probably pass 100,000 in the not too distant future.

How can we improve organ availability? Members of ASTS are continuously working in the trenches with our patients and also in investigational laboratories seeking:

- Innovative methods of improving the availability and quality of organs for transplantation;
- Ways to more successfully preserve transplantable organs outside the human body;
- Safer and medically acceptable ways to transplant from living donors kidneys, lungs, and liver and pancreatic segments;
- Methods of safely splitting organs from cadaver donors;
- Hastening the day when animal cells and organs will be available to replace their human counterparts using molecular technology;
- Working to advance our understanding of the human immune system.

We have already done some of this, in part, in using porcine heart valve replacement and skin for dressings for extensive burn coverage in critically ill patients.

We have extended our most recent initiatives this year into operational practice, in improving organ availability and in the most important component, education of the American public. These initiatives have taken two major directions.

Operationally, with our paramedical assistants and colleagues who have developed and administered the Organ Procurement Organizations in America, represented by the Association of Organ Procurement Organizations (AOPO), we are already adapting novel approaches to improve the identification of organ donors in donor hospitals, and in their physiologic maintenance, in order to significantly increase organ availability. This includes increasing consent rates by families of the donors using the practical approaches now in operation in Spain, as well as the organizational structure and practice in operation in Great Britain.

We did this after a week-long fact-finding tour of these countries last October. Our delegates—Dr. John Roberts of the University of California at San Francisco, Dr. Bruce Rosengard and Dr. Avi Shaked of the University of Pennsylvania in Philadelphia—worked with OPO representatives from Massachusetts, Minnesota, Florida, and California, as well as a representative of the former Partnership For Organ Donation. This working group then organized plans to adapt the application of these novel systems of organ donation and maintenance that had been in practice in these countries for the past several years, to set similar practices in place in demonstration regions in the United States.

We sought at the outset, and several times since, to involve the Department of Health and Human Services in these efforts. While they expressed interest, they thus far, for ill-defined administrative reasons, have been unable to help with the seed funding of the projects, which continue to develop with an enthusiastic response of our professionals.

We feel the potential exists to actually double the number of heart transplants available to Americans. There also could be an improvement in overall organ donation in our country by these activities from a rate of 19 donors per million to over 30 donors per million—a 50 percent increase that would enable us to provide a new chance at life to an additional 10,000 American men, women and children each year. I am pleased to provide formal reports outlining our progress in these two initiatives for your detailed study.

The second initiative is one of public education, now ten months into operation, and it is called the First Family Pledge Campaign. It was launched by ASTS last May and has as its honorary co-chairs Reg and Maggie Green, who donated their 7-year-old son Nicholas' organs and tissue after he was murdered in Italy in 1994.

The First Family Pledge Campaign now has the support of all of the organizations involved in increasing organ and tissue donation in America, who several years ago formed the Coalition for Donation. The whole concept of organ donation has not been well-defined, because the thoughts behind the process have not been clearly dissected and portrayed by us who know what we see in the trenches when consent for donation is requested and when life-saving organ transplants are performed.

Organ donation and transplantation are not, and should not be, individual acts.

They require the participation and support of the loved ones, the family close to the potential recipient who might die without the transplant, and the family of the potential cadaver organ donor, who must be included in this process, in order that they understand the opportunity of saving lives of many after the tragic, but inevitable, death of their loved one.

It is a family-to-family act of Americans who understand that we all ultimately are part of one human family.

In any family's time of need, all family members obviously hope a life-saving organ will become available in time. If we dare hope for this gift of life, how can we do less than make a family commitment, in return, to our brethren—to be there for them, if the circumstances ever arise, to save the life of their loved ones through the reciprocal act of organ donation.

We think this powerful concept—a family pledge, far better than the solitary, individual act of signing an organ donor card—has enormous potential.

Already, the First Family Pledge approach has resulted in more than twice as many Members of Congress publicly endorsing organ and tissue donation as ever before—a heartening surge in leadership support demonstrated yesterday by the First Family Pledge Congress which many Members attended.

This First Family Pledge activity is rapidly growing nationwide, and will continue with the help of yourselves as examples of First Families, pledging, if catastrophe ever occurred to your loved ones, organ donation, to fulfill the life-saving needs of others. First Family Pledge activities are now being organized in many American cities and communities, with the help of their mayors, and county executives, and city council leaders—their First Families. I also include an informational packet about this initiative for your perusal and would be happy to answer any questions that I can about organ donation in America.

Thank you.

Mr. BILIRAKIS. Thanks so much, Dr. Miller. Your emotions serve you well on this subject.

Mr. Brand?

STATEMENT OF JOSEPH L. BRAND

Mr. BRAND. Thank you, Mr. Chairman. Mr. Chairman, members of the committee, my name is Joe Brand. I am the volunteer Chairman of the National Kidney Foundation. The National Kidney Foundation is the world's largest private organization representing organ donors, transplant recipients, and candidates for transplantation. We speak for the more than 4,000 constituents of our National Donor Family Council who have had the personal experience of the gift of life and the more than 3,000 members of the NKF TransAction Council who have benefited from life-saving organ transplant.

Every other year, thousands of recipients of all solid organ transplants compete in the U.S. transplant games sponsored by the National Kidney Foundation. Finally, a large portion of the almost 10,000 members of the National Kidney Foundation Patient and Family Council are on the transplant waiting list. In all, the National Kidney Foundation represents 30,000 lay and professional volunteers from every walk of life and every part of the United States.

Mr. Chairman, you have already heard from Dr. Neylan that before the day is over, ten Americans will die for want of a transplant. We, the National Kidney Foundation, therefore salute this Subcommittee on Health and Environment of the Commerce Committee for its decision to put patients first and rally national attention to the need to increase the supply of organs available for transplantation.

Living organ donation is a bright chapter in the organ donation story. While the number of cadaveric organ donors increased by 33

percent between 1996 and 1998, the number of living donors grew by 95 percent during that same time period. The National Kidney Foundation believes that we have only begun to tap the potential of living donations.

Therefore, we are planning many new programs, including one, for example, called "Do You Have a Donor?" This program will reach out to patients when they are first diagnosed with chronic renal insufficiency which may eventually necessitate transplantation. It will present early on the option for many patients of a living related donation. It is designed to prepare the potential recipient and the potential donors for the process of considering a living donation.

This kind of private sector initiative offers a great deal of promise. Nevertheless, there are barriers to living donations which an organization like the National Kidney Foundation is not able to address. For instance, there are financial disincentives to living donations. Living donors are faced with a loss of income attributable to the time from work needed for evaluation, surgery, and recovery. There are also costs associated with their donation which are not reimbursable, for example, travel, lodging, meals, and child care.

Two seminal studies sponsored by the National Kidney Foundation's Council of Nephrology Social Workers shed some light on the extent of the problem of financial disincentives. In a survey involving more than 500 living related donors at nine geographically dispersed centers, almost 25 percent of the respondents reported that donation had caused a financial hardship. Another such study by the National Kidney Foundation's Council of Nephrology Social Workers was the first to explore financial issues at the time of the transplant. Approximately one quarter of the family members surveyed indicated that financial issues kept them from being donors.

The National Kidney Foundation encourages legislation to address the financial disincentives to living donation. We understand that Congressman Karen Thurman is working on such a measure. If Federal funds were available to remove financial disincentives to living donations, the superior graft survival rates associated with living donation would justify the expenditure. Furthermore, such payments are explicitly exempted from the prohibitions in Title III of the National Organ Transplant Act of 1984.

I would like to leave you with one final message. The availability of organs for transplantation would be enhanced if we could reduce the need to repeat transplants. At least one-eighth of cadaveric kidney transplant recipients have had a previous transplant and more than a fifth of the candidates for a kidney transplant have had one or more transplants already.

One reason why transplant recipients lose their grafts is that they cannot afford to pay for anti-rejection drugs after Medicare payment for these drugs ceases during the 3-year post-transplant period. The National Kidney Foundation, therefore, emphatically supports H.R. 1115, which would extend these Medicare benefits indefinitely and which was referred to your committee on April 7, 1999. I am very pleased to note that of the 82 cosponsors, many of your subcommittee members are on that list.

Mr. Chairman and members of the committee, I thank you for the opportunity to testify on behalf of the 30,000 people we rep-

resent, each one of whom has a vital interest in the subject matter before you. Thank you.

[The prepared statement of Joseph L. Brand follows:]

PREPARED STATEMENT OF JOSEPH L. BRAND ON BEHALF OF THE NATIONAL KIDNEY FOUNDATION

Mr. Chairman and members of the committee: I am Joseph L. Brand, chairman of the National Kidney Foundation, the world's largest private organization representing organ donors, transplant recipients and candidates for transplantation. The Mission of the National Kidney Foundation is to prevent kidney and urinary tract diseases, improve the health and well-being of individuals and families affected by these diseases and increase the availability of all organs for transplantation. In particular, the 4,229 constituents of our National Donor Family Council have had the personal experience of giving the "Gift of Life" and the 3,317 members of the NKF transAction Council have benefitted from a life-saving organ transplant. In alternate years thousands of recipients of all solid organ transplants compete in the US Transplant Games sponsored by the National Kidney Foundation. Finally, a large proportion of the 9,354 members of the National Kidney Foundation Patient and Family Council are on transplant waiting lists. In all, NKF represents 30,000 lay and professional volunteers from every walk of life and every part of the United States.

Mr. Chairman, before the day is over ten Americans will die for want of an organ transplant. The National Kidney Foundation, therefore, salutes the Subcommittee on Health and Environment of the Commerce Committee for its decision to "Put Patients First" and rally national attention to the need to increase the supply of organs available for transplantation. For its part the National Kidney Foundation is redoubling its efforts to increase organ donation by establishing a new supporting organization, "Transplant America," which will be a vehicle for a new focused effort to more effectively bring our resources to bear in a serious and thoughtful way on the terrible organ shortage we face.

Living organ donation is a bright chapter in the organ donation story. While the number of cadaveric organ donors increased by 33% between 1988 and 1996, the number of living donors grew by 95% during that same time period. That National Kidney Foundation believes that we have only begun to tap the potential of living donation. Therefore, NKF and Transplant America are planning many new programs, including one, for example, called "Do You Have A Donor?" This program will reach out to patients when they are first diagnosed with chronic renal insufficiency which may eventually necessitate transplantation. It will present early-on the option, for many patients, of a living related donation. It is designed to prepare the potential recipient and the potential donors for the process of considering a living donation. It also raises the issue in an up-front and honest manner so that living donation can be considered by more potential donors and recipients.

This kind of private sector initiative offers a great deal of promise. Nevertheless, there are barriers to living donation which an organization like the National Kidney Foundation is not able to address. For instance, there are financial disincentives to living donation. Living donors are faced with loss of income attributable to the time away from work needed for evaluation, surgery and recovery. There are also costs associated with their donation which are not reimbursable, for example, travel, lodging, meals, child care, etc. Two seminal studies sponsored by the National Kidney Foundation Council of Nephrology Social Workers shed some light on the extent of the problem of financial disincentives. In a survey involving more than 500 living-related donors at nine geographically dispersed centers, almost 25% of the respondents reported that donation had caused a financial hardship. Another CNSW study was the first to explore financial issues at the time of the transplant. Approximately one quarter of the family members surveyed indicated that financial issues kept them from being donors. In this study the University of North Carolina Transplant Program contacted 124 patients and 108 family members over a one year period. The National Kidney Foundation encourages legislation to address the financial disincentives to living donation. We understand that Congresswoman Karen Thurman is working on such a measure. If federal funds were available to remove financial disincentives to living donation, the superior graft survival rates associated with living donation would justify the expenditure. Furthermore, such payments are explicitly exempted from the prohibitions in Title III of the National Organ Transplant Act of 1984.

There are other disincentives to living donation which are perhaps less well documented. For example, there is anecdotal information indicating that living donors

may experience discrimination in obtaining health and life insurance. We need to determine the degree to which these are access problems and to explore ways to address these barriers.

I would like to leave you with one final message. The availability of organs for transplantation would be enhanced if we could reduce the need for repeat transplants. At least one-eighth of cadaveric kidney transplant recipients have had a previous transplant and more than a fifth of the candidates for a kidney transplant have had one or more transplants already. One reason why transplant recipients lose their grafts is that they cannot afford to pay for anti-rejection drugs after Medicare payment for these drugs ceases three years post-transplant. The National Kidney Foundation emphatically supports H.R. 1115, that would extend these Medicare benefits indefinitely and which was referred to your committee on April 7, 1999.

Mr. Chairman and Members of the Committee, I hope that our testimony has provided a new perspective on the problem of the supply of organs for transplantation in the United States. I would be pleased to answer any questions you may have or to provide any additional information that the committee may request. Thank you for the opportunity to testify here today.

Mr. BILIRAKIS. Thank you so much, Mr. Brand.

We have heard testimony this morning about a myriad of programs in effect in States to increase the supply of organs. We have heard testimony that there has been a lot of progress made, far from enough, to be sure, but progress has been made. We have heard testimony more recently from Mr. Brand and others about incentives for people to donate their kidneys, and some incentives in Pennsylvania and other States.

Things are nowhere near where they should be, and there is a role that Congress should be playing. We have to figure out what that role is or what that role should be and take into consideration so many factors.

I just worry that since there is progress, if we make any great changes in the current picture, what that might do. So the question is, if we were to move to a national waiting list system, which, as you know, the administration is proposing, would we be destroying the incentives that States have crafted policies to increase organ supplies? I think that is critical. We are concentrating now on finding ways to better that supply. But no matter what we come up with, if it is set back because we change the current system of allocation, then we are right back where we started from or maybe even worse off.

Mr. Campbell, those of you who talked about what is happening in the particular States, if you have been in the audience when we have had organ allocation discussions, you know that I have raised that as my biggest concern about change. Florida, for instance, now has a pretty good record in this regard. The State would be conceivably losing its incentive to do even better if this national waiting system were to go into effect. I would like to hear from all of you. Yes, Dr. Miller?

Mr. MILLER. Congressman Bilirakis, I happen to agree with you. There are certain improvements and this will be the subject for an intense discussion tomorrow at the Institute of Medicine that Dr. Ronald Busuttil will be representing our Society, directing the largest liver transplant program in the United States. He is our President-elect.

But there are certain problems that will be brought up with a national list that I think I can speak to that have to do with the disincentives that were not mentioned in the OPTN rule and they have to do with the fact that professionals in organ donation are

very frequently motivated by local factors, by the success rate of their own transplant programs and those close to them, by the pressures put upon them by the transplant professionals in those centers. They get to know their own organ transplant potential recipients. They get to know them very well. There are these local factors that have to be taken into account. To nationalize this whole system is not to think of it in specifics but in generalities, and that is dangerous.

Mr. BILIRAKIS. Thank you, sir. Any further comments, as briefly as you can because I would like to hear from as many of you as I can within my period of time. Mr. Campbell?

Mr. CAMPBELL. I would agree with Dr. Miller. A number of us have said this morning that organ donation is a local phenomenon. It is a community phenomenon, and to a large degree, it is a personal phenomenon. LifeLink definitely feels that a process such as has been contemplated of complete national sharing would be a disincentive to the kind of efforts that have increased organ donation so dramatically in the State of Florida.

Mr. BILIRAKIS. Dr. Marcos, I know you are anxious to comment.

Mr. MARCOS. Yes. I think we are the living proof of what surgeons have to do to meet this shortage of organs. A program like ours, if new rules come around, will mean even less organs for our region. Doing a living donor liver is a major, major surgical procedure, putting a healthy donor at risk. So I speak for my program and I think that any changes, like you say, in the current allocation of organs might jeopardize at least the citizens in our State.

Mr. BILIRAKIS. Thank you. Dr. Neylan, do you have any comment?

Mr. NEYLAN. As I said in my testimony, I think the issues surrounding allocation are extremely difficult. This has been a deliberate process which has engaged the transplant community, broadly defined, and I think it is a process which has to continue in that manner.

The allocation of this scarce resource for the various types of organs is far from perfect, but it is, nonetheless, the best system we have so far. We continue to look very carefully, all of us in every part of the country, to address the concerns that have been raised, concerns about inequities in waiting times, concerns about whether patients just across the river have a better access to an organ than on the other side of the river.

These are very important issues, but these are issues that have to be entertained by the transplant community in partnership with the Federal Government, State government, and all the other parties that are a part of this process. So I would continue to reiterate, as I believe the others have said before me, that that process needs to go forward in that manner and that spirit.

Mr. BILIRAKIS. Dr. Metzger?

Mr. METZGER. Mr. Chairman, I could only second what Dr. Miller and Mr. Campbell said. In Florida, we have five of the most successful organ procurement organizations in the country and each of them developed with an individual transplant program, illustrating the successful efforts that can be made when that is a local issue and the programs are working together to provide the organs for their patients.

Mr. BILIRAKIS. Mr. Nathan, I did not mean to skip you. I did not know whether you had anything to offer.

Mr. NATHAN. Well, those of us in the organ donor field feel very stressed by the fact that this has become a public issue, in that the whole system is based on public trust. The transplant community has, as Dr. Neylan said, really debated this in an imperative way. In other words, we get data, we look at it, and we relook at the allocation process. But to come in and sort of mandate a one-size-fits-all type of policy is very scary to those of us in the community, and I think secondarily, perhaps disrupting this public trust by publicizing this debate.

Mr. BILIRAKIS. I appreciate the indulgence of the subcommittee. I have gone over my time, but this is really a very important point, I think, for all of us. I know, Dr. Higgins, you would like to be heard very briefly.

Mr. HIGGINS. Just very briefly, in my opinion. We serve a large African-American community and we are concerned that any change in the allocation scheme which advantages local centers may, in fact, disadvantage African-Americans or socio-economically disadvantaged people by sending organs away from local centers.

So I think it is a real concern for us in Detroit. We transplant 20 percent of our patients, the recipients are African-American. They may not have access to adequate high-quality transplant procedures if the organ allocation system shifts organs away from local medium-sized and small centers to large regional centers. I know that most of our patients could not get up and fly to a large center and be able to be on the list and sit there and wait. So I think it is a major issue from that standpoint.

Mr. BILIRAKIS. Mr. Brand, do you have anything you want to offer?

Mr. BRAND. Yes, Mr. Chairman, if I might. Our organization represents both donors and transplant recipients and we recently polled them as to how they view this issue. Essentially, they prefer the local issue, the local option. We await the Institute of Medicine study on it, but that is the view of the people who—

Mr. BILIRAKIS. I am not going to ask you to respond to this, but I have to wonder. You are all leaders in the field here and I know that there are others, too, who have different opinions. I just would hope that you have made your opinions known to the administration and particularly to your Members of Congress, your Representatives. That is just very critical because we can be spending so much time up here coming up with new ideas and then get actually set back rather than continue to go forward.

Mr. Brown?

Mr. BROWN. Thank you. First, I would like to ask unanimous consent that the record be held open for written comments to the witnesses from any members and opening statements, and there is a statement, also, if I could make this request even longer, from Congressman Stark to be entered into the record.

Mr. BILIRAKIS. Without objection.

Mr. BROWN. Thank you.

[The prepared statement of Hon. Pete Stark follows:]

PREPARED STATEMENT OF HON. PETE STARK, A REPRESENTATIVE IN CONGRESS FROM
THE STATE OF CALIFORNIA

Mr. Chairman, I wish to commend you for convening this essential hearing on organ donation and thank you for allowing me to enter this statement.

As you are well aware, there is a serious shortage of viable organs for transplant. Over 50,000 people are currently waiting for a transplant operation. Because of low donor rates, over 4,000 people die each year for lack of a suitable organ.

We need to use every possible means to increase the number of donated organs for all Americans. Earlier this year, I introduced the "Gift of Life Congressional Medal Act of 1999" (H.R. 941). Senator Frist introduced the same legislation in the Senate. This legislation sends a clear message that donating one's organs is a selfless act that should receive the profound respect of the Nation.

This legislation would allow the Health and Human Service's Organ Procurement Organization (OPO) and the Organ Procurement and Transplantation Network to establish a nonprofit fund to design, produce, and distribute the Gift of Life Congressional Medal. Funding would come solely from charitable donations.

The donor or a surviving family member would have the option of receiving the medal.

Families would also be able to request that a Member of Congress, state or local official, or community leader award the medal to the donor or donor's survivors.

According to the United Network for Organ Sharing (UNOS), an average of 5,300 donations per year was made between 1994 and 1996. Research points to a clear need for incentive programs and public education on organ donation. These efforts can increase the number of organ donations by more than 80%.

This legislation contributes one solution to a complex problem. Creating the Gift of Life Congressional Medal establishes in unambiguous terms the importance of organ donation. In addition, the medal represents this Nation's profound thanks to those who actions save the lives of others. By appropriately acknowledging the importance of organ donation, we anticipate greater levels of participation in donation programs. This noncontroversial, nonpartisan legislation will do much to increase organ donation. Therefore, I ask each of you to help support this legislation.

I hope that your deliberations will be productive and identify additional ways of increasing the availability of organs for transplant.

Mr. BROWN. Mr. Nathan, you said something a moment ago about the government being involved in this. I would ask you just one question about that. Understanding that doctors and hospitals want to make these decisions but government pays for roughly half the cost, I believe nationally, of transplants, does the Louisiana State law, or the organ hoarding law that they have, disturb you as much as the Federal HHS getting involved in this issue?

Mr. NATHAN. Well, I do not want to comment necessarily on Louisiana. I do not know the state of that situation.

Mr. BROWN. But you do know that they have a State law that, as much as possible, keeps their organs in-State, although they do not seem to mind people in their State getting organs from other States.

Mr. NATHAN. Right. Just so you know, where I am coming from is that I represent a large regional program and we advocate sharing. The question that lies is to what extent. At what point do you share organs? In other words, is it for the sickest patient 3,000 miles away? Is it for someone who has been on the list an hour longer? These are sort of the problems that occur when you start trying to mandate a national sharing system. And I do not think many of us at the table are beyond sharing, because there are a lot of sharing systems. Florida, for example, has a State-wide sharing system.

So my point is that I do not advocate State laws that keep organs within a State. I do not think that is a good policy, particularly one who works within three States. But I think the reality is that they are complex and the fear is that for the government to mandate a

system, and knowing how long sometimes it takes for things to change, this is a very interactive process. It changes on a 6-month basis and the system may need to change quicker and respond to patients' needs quicker than perhaps some sort of policy like that. I think that is the fear that everybody at this table has.

Mr. BROWN. Okay.

Mr. NATHAN. Did that make sense to you?

Mr. BROWN. Yes, it makes sense. I think we temper that by understanding that taxpayers are paying for a lot of this and that our health care system, to sort of allow doctors and transplant centers and hospitals to sort of unilaterally make these decisions without some sort of public involvement is not right, either, and that we need to come to some understanding that there needs to be a consensus and a sharing there of decisionmaking.

Mr. NATHAN. I think I totally agree with that and I think the idea is that it is trying to build consensus, but it is a very difficult issue to mandate some sort of policy that may affect local programs. I think the biggest fear is not knowing the outcome.

I have advocated—I actually wrote testimony last June to this subcommittee to basically say that I thought the best way to handle this is to suggest some changes and try a pilot program for 3 years and then look at the information, because one of the problems in modeling is you cannot feel the outcome. I think if people knew there was a limit to testing a new sharing procedure, that may help alleviate some fears.

Mr. BROWN. Okay. Dr. Metzger?

Mr. METZGER. Congressman Brown, I would just like to make a comment regarding the taxpayers' payments. There is no doubt that if you increase sharing, you increase a number of things that increase cost. All of us voluntarily share when it is very appropriate to do so and beneficial for our patients and that has been an ongoing thing in transplantation.

When you share across longer geographic areas, the cold ischemic time goes up dramatically, and Dr. Mark Schintzler, who you may want to get testimony from at some time, at Barnes Hospital in St. Louis has excellent data combining the USRDS and UNOS data systems, showing that for every hour of cold ischemic time, you increase the cost of transplantation for that patient \$100 per year per patient life. So increasing cold ischemic time is very bad. Nationally right now, it is about 5 hours' difference between local and sharing programs, and so that is \$500 per patient per year in costs that the taxpayer has to pay when you go to a more nationwide sharing system.

Mr. BROWN. Let me shift. Can I have another couple of minutes, Mr. Chairman? That is a pretty quick 5 minutes.

Mr. BILIRAKIS. Yes.

Mr. BROWN. Thank you. Dr. Marcos and Dr. Higgins, if I could ask you something totally off of what I just mentioned. I am sorry I did not hear your testimony, Dr. Marcos. I read your testimony. I had a high school group out in the hall that I had to talk to you. Both of you, and Dr. Higgins, you mentioned in your oral testimony about pediatric recipients and trimming down and splitting and what you can do with that. Could you, and I hate to make it this quick, but could you just sort of run through sort of what all of that

means in terms of which kidneys you can do that and understanding difference in size with children and with adults? Could you kind of run through that briefly, each of you?

Mr. MARCOS. Yes. We are talking about livers. In the beginning, the problem was to get organs for pediatrics, for kids. So surgeons started cutting down livers to accommodate those small bodies and the rest of the liver was thrown out and wasted. Therefore, you are only benefiting one patient.

Then this new technique, splitting the liver came, in which you cut the liver in two, you put the biggest part on the adult and then the smallest, because the liver is not a symmetrical organ, the smallest goes to another pediatric or very small adult. So that is splitting of organs. You are benefiting two recipients out of a single organ, though it is very hard to do. Maybe Dr. Busuttil, who has a lot of experience, is here today with us, but it is very hard to do and all the counties that we do it and maybe a community hospital in the middle of the night. But anyway, that solved that problem.

Nowadays, it is the adult, the recipient that is suffering from the shortage of organs. The pediatric recipients are more or less covered, mostly from living donors. That is done in a lot of centers in America. Then came the idea of living donor from adult to adult in which you take a big portion of the liver, the right side, from a living donor to a recipient.

So those are the three techniques that surgeons have been forced to, because if we had organs, we would rather take a cadaveric organ of the same size and put it into the recipient. We do not, so those are the three techniques that we presented or talked about today.

Mr. BROWN. Is there anything you want to add to that, or does that cover it?

Mr. HIGGINS. That basically covers it, I think, but it is only for livers that this technique could theoretically be utilized. You cannot do it for the heart.

Mr. BROWN. Thank you.

Mr. BILIRAKIS. Mrs. Cubin?

Mrs. CUBIN. Thank you, Mr. Chairman. I do have a statement to submit for the record.

Mr. BILIRAKIS. Without objection, we have already gone through that.

Mrs. CUBIN. Thank you.

I am married to a physician and probably have more experience in dealing, or at least in knowing about transplantation, both patients and donors, than a lot of people. As a matter of fact, when I was in the State legislature some 10 or 12 years ago, the very first month I was there, a woman came to the legislature with her 14-year-old daughter that needed a kidney transplant, asking the legislature to pay for that transplant because her daughter would die. That was a real eye opener. We checked into the number of people in Wyoming who were waiting for transplants. There were 17, and had we financed all of them, it would have literally bankrupted all at once our entire Medicaid budget. It was very difficult at that time.

Having said that, it seems to me that, really, one of the biggest problems, or at least a big problem in getting an adequate number

of organ donors is education, public education. I right now have no idea—I mean, I would be glad to give anybody anything I have got when I do not need it, but I have no idea if any of my organs, at my age, in my physical condition, would even be desirable to someone, and I think that a lot of people, once they get over the age of 40—I know you cannot believe I am over 40——

Mr. BILIRAKIS. That is correct.

Mrs. CUBIN. Do not laugh. But I think a lot of people really do not know that. And so public education, in my mind, is very lacking as far as organ donors. Who do you think should be responsible for that public education, at what level? Should it be in the local community? I can see going into high schools, to colleges. My son when he was in high school said, "No way would I ever want any of my organs to be donated." Now he is in college and he says, "Yes, that would be great." Who should take the lead in educating the public about organ donation? Dr. Miller?

Mr. MILLER. I have just a few comments. I totally empathize and sympathize with what you have just said. It is fascinating because the public in general believes that if they sign an organ donor card, that means that their organs are going to be taken. It is impossible to do. That is why we took it as an initiative to start this First Family Pledge campaign because it is a family-to-family thing.

But the educational process, if this is going to become part of the American culture, to be an automatic in our thinking, something very simple, we are organ donors, it has to be done from the lower school grades upwards. There has to be institution in our formal educational schooling that organ donation is part of what we do in life. That requires State, Federal, local. Who does it? Lots of people do it. Can it be better organized? You bet.

Mrs. CUBIN. Mr. Nathan?

Mr. NATHAN. That is a very good question because the answer is you have to do it all, and the concept of creating a Coalition on Donation, which represents both public and private organizations, is to get each of their organizations to promote organ and tissue donation. So the Federal Government has adopted the Coalition on Donations "share your life, share your decision" initiative. The Coalition has partnered with the Ad Council to do public service announcements. Michael Jordan volunteered his image to reach children and sports fans.

So the answer is, you have to put the message in every level of society. Some State programs, for example, like in Pennsylvania, where I am from, we are putting the message into secondary schools, so that we are taking some of these creative tools that were created by these national groups and then implementing them at the local level. So it is a top-down, bottom-up approach.

Mrs. CUBIN. Just to get my opinion on the record about the national waiting list, I know in all the communities in Wyoming, if someone thinks that their organ or their family's organ will go to someone in the Rocky Mountain State, they are much more likely to help their neighbor or someone in their community. They are much more likely to go that far than to think that it might go someplace in New York, because, you know, if you are from Wyoming, you think everybody from New York is a little weird anyway. You are not even sure your liver would fit.

I have one question. This is just curiosity. When you are talking about dividing a liver between an adult and a child and the smaller portion being transplanted into the child, then does that liver grow with the child as the child grows?

Mr. MARCOS. Yes. And, actually, in adults, too, we have proven that within around 7 to 14 days after transplant, the liver grows back to the full size, which makes living donation of livers such an important fact. If you donate a kidney from a living donor, the kidney does not grow back. The liver does, and it does pretty fast, and as those kids you saw this morning, today, it will grow with them. It is a wonderful organ.

Mrs. CUBIN. And how about the pancreas?

Mr. MARCOS. There has been some experience with living donor pancreas, though that has not been well established. The organs usually do not increase in size. The kidneys do suffer some hypertrophy in function but do not do the same phenomenon as livers do.

Mr. MILLER. You are really dealing with a very dynamic field here. Things have even changed in the past few years. There is so much in the way of scientific or medical advances. When you ask a question about can a pancreas increase in size, what one is dealing with in a pancreas is transplantation to replace the need for insulin in diabetics, which is such a devastating disease.

There are ways now of culturing the islets of langerhans, which make insulin. There are ways perhaps of even introducing growth factors into this culture so that these cells can enlarge and proliferate. This is all dynamic. Were you to ask this question 3 or 4 years from now, you would probably get a different answer.

Mrs. CUBIN. Thank you, Mr. Chairman.

Mr. BROWN. Mr. Chairman, I would like to just comment. I was saying to the chairman, and this may sound a bit inappropriate, but my friend from Wyoming saying that a Wyoming person may not be so predisposed toward donating an organ to someone from New York, would someone from Wyoming be happy to receive an organ from someone in New York if it came to that? I just am not sure I believe——

Mrs. CUBIN. I did not say that they would not want to do that. I am saying that they would be more likely to want to give it to someone if they thought it would be in their community, in their area, that there would be an emotional desire, just a feeling of community.

You know, I am absolutely convinced that the old barn raising mentality that we still have in the West, where neighbors help neighbors, people in communities build communities instead of having the government do it. I am absolutely convinced that that is what will save this country, and I think it is that attitude.

You start with your family, your city, your county, your State, and you go out as far as you can and be as generous as you can with the resources that you have. But I just think instinctively that if I knew or if someone knew it was going to go to someone in their area, they would be more likely to do it, thus having more organs available. But certainly the country is part of our community, and I did not mean to be disparaging that way.

Mr. BROWN. No. I——

Mrs. CUBIN. I just think it is more likely that people would donate if they thought it would go to their community.

Mr. BROWN. Do you think that is largely regional or part racial or do you think that going to Cheyenne is okay, but Denver is not, or Chicago is too far, or—

Mrs. CUBIN. I think it has something to do with—pardon me?

Mr. BROWN. Cheyenne is okay if you live in Casper, but Denver is not, or maybe Denver is and Chicago is not?

Mrs. CUBIN. No. No. I think anyplace in the Rocky Mountain region. It depends at how big you look at your community. But it does not matter if you live in Casper and the organ is needed in Cheyenne or Denver or New York if the donor is not going to give it. It does not matter.

Mr. BILIRAKIS. Mr. Greenwood?

Mr. GREENWOOD. Thank you. One thing we would never want to see is a Republican organ donated to a Democrat. That would be beyond the pale. I think we should separate them that way first.

First off, I apologize for being absent for some of your testimony. One of the rites of spring here in Washington is that the school groups come down and they expect you to go see them, and so Mr. Brown and I, at least, and others have to run out and do that from time to time.

But it was illustrative as I was talking to the students about what I do and I was telling them that I was at a committee hearing about organ donation and I tried to outline the problem a little bit to them, three interesting responses. One student said, well, is it not true that if you sign up as an organ donor, they will not save your life in the hospital? So I tried to disabuse her of that information. Then one of the fathers proudly pulled out his Pennsylvania driver's license and showed that he was an organ donor. Then one of the students said, well, they wanted an extra dollar to do that and I did not have the dollar so I did not sign up to be an organ donor.

That raises the issue of we know, and we have known for a long time that there is this tremendous differential between the demand and the supply of organs. We have tried a variety of things, and you gentlemen have all been terrific at making your recommendations and I have looked at your testimony.

The question of financial incentives has always been sort of a very hard, bright ethical line that is drawn, that you do not want to tie any financial incentives, to create an incentive using financial means. And yet there has been some inching across of that line. In Pennsylvania, as I mentioned, I think that with the \$1 that goes to the driver's license, there is a fund, and now we pay \$300 toward the funeral arrangements for a donor. I do not know if anybody has ever donated an organ for the \$300 that might go to their funeral. I would be surprised, but maybe they do.

When HCFA creates a condition of participation in Medicare and Medicaid, that is a huge financial incentive. I mean, make no mistake about it, you will do this or we will withhold maybe millions of dollars from you. So that is certainly the use of a financial incentive.

As I mentioned in my opening statement, my constituent, Mr. Epstein, who has been sitting patiently here, he believes that what

we should do is that the Federal Government should, as a matter of law, essentially create an insurance policy, in his proposal, \$10,000, that would go to the family of anyone who donated their organs. He thinks that that is benign, that no harm can come from that and that, in fact, a tremendous good could come of that, that that would be the level of financial incentive that would wake a lot of people up and say, hey, \$10,000 to my family is a significant chunk of money. He believes that if the Federal Government were involved in that kind of a financial incentive program that, in fact, we would save a lot of money because we would save a lot of payments of Medicaid and perhaps Medicare payments that are made to hospitals for people who wait for organs.

I would like each of you in the time that remains to give me your thoughts about financial incentives in general or the specific program that I have set forth in specific. Just jump in. I will start with my regional guy, Mr. Nathan.

Mr. NATHAN. It is good to see you. You know, when this was proposed in Pennsylvania in 1994, it sort of had no debate at all. I mean, it just sort of snuck through to become law and it has taken this much time to buildup these funds to this point where we can just give this nominal amount of money toward funeral expenses. It was really directed by a legislator who came to the point where families that he knew felt that they would not have money to bury someone and if there were a donation involved, an organ donation, maybe there was a way for them to benefit. It was a very sort of innocent thing that was thrown in at the last hour in this law.

What is interesting about it, when this hit the newspapers yesterday, we had calls from all over the country because it is a novel idea. The biggest fear, I think, that transplanters have, and there are certainly a lot of people at the table who can comment, is crossing that line from true altruism—it has always been called the gift of life—to that which folks concerned that organs, would be bought and sold, in essence.

That is not the idea here. I do not think it is Mr. Epstein's idea to do that, either. The idea is for folks to have some small benefit, and again, I do not know how large that benefit should be, whether it is Mr. Epstein's plan or whether it is this small funeral expense. I do not know.

The reason why I think the question has to be asked is because we have never answered the question, and that is why this pilot program, I think, will be very important, to determine if it has any influence not only on donors but people who did not donate, to see if it had any fact at all in their decision.

So I think the question has been asked and now it is going to be tested. Certainly, other people can comment on the rationale behind not wanting it in the transplant community.

Mr. GREENWOOD. Mr. Brand?

Mr. BRAND. We have looked at this issue with our constituents and the bottom line is, we would support at least a pilot study on financial incentives. When I became the volunteer Chairman of the National Kidney Foundation 18 months ago, I convened a group of outside business people and said, here is the problem. Cadaveric donations are flat. Demand is going like this. We have been in this business 50 years. One of our mandates has been public education.

Guess what? If we were in business, we would have to commit bankruptcy right now because we just have not changed the numbers. I have not heard a bad idea here today. Every one of these ideas is a very good idea, I think. The problem is implementation.

What we decided was we had to focus. We had to raise a pile of money, set up a foundation within our foundation focused only on changing the numbers. We are committing to do that in 5 years. We are trying to raise \$25 million to implement a lot of the programs. The Pennsylvania law that Dr. Nathan has talked about has been now transplanted itself to Maryland, Texas, elsewhere. It certainly is working. We ought to have a model law for all 50 States doing that. Financial incentives, if we have any data that says they are working, we ought to try them elsewhere. So we certainly would support that.

Mr. GREENWOOD. Thank you.

Mr. NEYLAN. I would like to speak to that, as well. I guess partly from my scientific training, I look at the idea of piloting as a natural methodology, that, indeed, as we take on these new ideas, we should test them, and we should test them in a small and controlled fashion. That is No. 1.

But two, after we have tested them, let us look at them critically and let us compare them with other experiments. If there is good news there, let us expand it. Let us support it and let us develop it further.

The Pennsylvania law of \$1 going to a fund—great idea. Georgia took a slightly different idea. They said, let us take \$2 off. Anyone that wants to be an organ donor can get their renewed driver's license for \$2 less. That is the same thing, really. The State is still supporting this financially. It sends a good message. It is early. We cannot really speak to the results yet. But it is a pilot and we are looking at it. We need to learn from these things.

I think our message today ought to be that we need to be creative in the approach to organ donation. We need to be open, even to the idea of financial incentives, but it needs to be done carefully.

Relating to financial incentives, let us turn that on its ear. What about disincentives? Again, in my testimony, I mentioned our support of Congressman Cummings' bill which would extend the Federal leave for Federal employees who are organ donors. There is a real financial disincentive to being a living donor. As Mr. Brand has suggested, if we can do more to remove those disincentives, we will also, I believe, encourage perhaps one of the most effective and cost effective means of increasing organ donation today, that is, increasing the living donors.

Mr. BILIRAKIS. Very briefly, Dr. Miller. I do not mean to cut you off, but we need to wrap up.

Mr. MILLER. The only point I wanted to make was that we are again dealing within a changing world. If you would have asked this question 25 years ago when transplantation was still in its heyday, it would have been an absolute no. The ethics would have forbidden it. Well, I do not know if ethics change, but somehow or other culture and outlooks change, and now we know that it is better for our society to have more organ donors.

So I would echo everything that has been spoken here, but I think you have got to look at this again and again and again, and

that is why something that is just going to be stamped as a great leveling, as a generalization, cannot be written in stone. It has got to be continuously reexamined, and that is what all of us are doing.

Mr. GREENWOOD. Thank you all.

Mr. BILIRAKIS. Dr. Coburn?

Mr. COBURN. Mr. Chairman, I have nine questions and there is no way I am going to get all these gentlemen to answer them. I would like permission to submit those and ask if you would please answer in writing these questions that I have. They have to deal with local transplant sites, they have to do with organ availability, they have to do with the new Federal guidelines, and I would like your expert opinion on each of them.

Mr. BILIRAKIS. Yes. We always ask the panel if they are willing to receive written questions and respond in writing. You have nothing else at this point?

Mr. COBURN. No.

Mr. BILIRAKIS. I guess that finishes up. This is a fascinating subject, a very, very significant one, obviously. It is life or death. I was just telling Mr. Brown a few minutes ago how I just wish we could focus on things up here, but you do not have that kind of a luxury, unfortunately. You have got to go from one problem to another to another to another.

Your being here today has been a tremendous help and I would request that you not only, of course, be available to answer written questions in writing, but additionally, if you have anything additional you want to offer us, additional ideas on how maybe we can attack this problem in addition to what you have already told us, which has been so valuable, please do not hesitate. We would be very receptive to it.

Thank you so very much for being here. God bless you for your great work.

The subcommittee is adjourned.

[Whereupon, at 12:15 p.m., the subcommittee was adjourned.]

[Additional material submitted for the record follows:]

PREPARED STATEMENT OF HOFFMANN-LA ROCHE

In recent years, demand for organs has increased as the medical community has developed new and better ways to treat transplant patients. However, organ donation rates have not kept pace with demand, leading to a national shortage of organs available for donation. According to UNOS, there has been no change in donation rates between 1996 and 1998. At the same time, the number of individuals on the organ waiting list increased by 13 percent between 1996 and 1997. More than 4,000 patients died while on the waiting list in 1997. As of June 1998, 56,222 individuals were awaiting an organ. Of the 2.1 million people who die in the U.S. each year, 12,000-15,000 could potentially be organ donors.

The causes of the organ shortage are multiple and varied. Barriers to donation include public misconception regarding the donation process and the definition of brain death, and the failure of potential donors to communicate their wishes to their families. A 1993 Gallup Survey sponsored by the Harvard School of Public Health, the Partnership for Organ Donation and 17 Organ Procurement Organizations (OPOs) showed that the majority of those polled would donate a relative's organs if they knew of the individual's wish to be a donor. However, relatively few individuals have informed their families of their desire to be a donor. It is for this reason that Roche supports the American Society of Transplant Surgeons (ASTS) First Family Pledge. This effort to encourage community leaders, such as members of Congress, to commit to be an organ donor and to discuss this commitment with their families can only serve to raise the issue of organ donation and the importance of sharing one's wishes.

A related barrier is that hospital workers are not often trained in the sensitivities needed when approaching grieving families about donation. Unless the families of potential donors are approached in a sensitive, caring way, they will be more likely to reject the donation option. The Department of Health and Human Services (HHS) issued a rule on June 17, 1998 requiring that all individuals in a hospital setting requesting organ donation be trained through a certified program administered by their local OPO. In addition, the rule requires hospitals participating in the Medicare program to report all deaths and impending deaths to the OPOs and eye/tissue banks. This rule is modeled after legislation enacted in Pennsylvania, which state officials estimate has increased organ donation rates in the state by 40 percent. HHS officials hope that the new rule will increase organ donation rates by 20 percent nationally. However, under current law hospitals participating in Medicare are already required to inform all families of the organ donation option. Some transplant experts believe that, unless HHS actively enforces this new rule, hospitals simply will not comply with the requirement. In addition, merely complying with the requirement does not ensure that appropriate techniques will be employed. A commitment on the part of hospitals and adequate training of personnel are essential to realization of this goal.

Another barrier to donation is individuals' misconception of their church's attitude toward organ donation. Many people believe that their faith opposes organ donation. However, a recent publication by UNOS and the South-Eastern Organ Procurement Foundation (SEOPF) shows that the major U.S. religious denominations either support organ donation or leave the decision to the individual.

These varied issues suggest that numerous initiatives need to be developed to try to increase the supply of organs for transplant. In addition, mechanisms for measuring the effectiveness of these initiatives should be developed. This is important for the purpose of justifying the expenses associated with efforts to increase donation and for the purpose of duplicating and expanding these initiatives. For example, numerous States and OPOs have developed innovative strategies for increasing organ donation, but in some cases there have been implementation problems or a failure to duplicate successful programs.

Not only are innovative efforts to increase donation needed, but we must caution against actions which could inadvertently result in fewer donations. One such issue is the recent HHS rule regarding the allocation of organs. Organ allocation is a uniquely complex matter, encompassing medical, economic and ethical issues. Given this complexity, we urge that any proposal affecting the current allocation system be grounded in the patient's best interest. Accordingly, the transplant community should be full participants in any decisions regarding the allocation of organs. Ultimately, it is the transplantation community, patients and their families that truly can make the most equitable determination regarding the distribution of the short supply of organs.

The Institute of Medicine (IOM) has been directed by Congress to examine both the current Organ Procurement and Transplantation Network (OPTN) policies and the HHS rule. The IOM must evaluate the impact of the OPTN policies and the HHS rule on: access to transplantation services by low-income and minority populations, organ donation rates, the ability of OPOs to sustain donation rates, waiting times for organ transplants, patient survival, and the cost of transplantation services. Further action on this issue should await the IOM report and recommendations. We look forward to the IOM analysis.

In addition to expanding organ donation, efforts must be taken to maximize the quality of life of individuals who have received a transplant. Currently, Medicare covers immunosuppressives, following a Medicare-covered transplant, for three years. In 1986, Congress enacted Part B coverage of immunosuppressives for one year. The Omnibus Budget Reconciliation Act of 1993 (OBRA 93), extended this coverage to three years. Transplant recipients must take immunosuppressive medication every day for the rest of their lives. Failure to take these medications significantly increases the risk of the transplanted organ being rejected. According to the United States Renal Data System, Medicare spending for dialysis patients average \$49,000 per year. First-year expenses associated with a kidney transplant average more than \$100,000. Medicare pays for the majority of kidney transplants performed in the country (more than 8,000 of the approximately 11,000 in 1995, according to HCFA). Elimination of the time limitation for immunosuppressive coverage will further protect this enormous investment already made by Medicare.

Transplant recipients have faced an anxious ordeal as their disease progressed and they waited for a suitable donor organ. These individuals should not have to experience the ordeal of how to pay for their medications in order to sustain their organ and lead a productive life. Successful transplants are important not only to the recipients but to donor families as well. Taking efforts to ensure that transplant

recipients lead long and productive lives with their new organs recognizes the generosity of those donors and their families who have given the gift of life. The inability of transplant recipients to maintain their organs, resulting in multiple transplants, could negatively impact the effort to increase organ donation.

For all these reasons, Hoffmann-La Roche is one of the founding members of the Immunosuppressive Drugs Coverage Coalition whose goal is to support legislation to eliminate the three-year limit on Medicare coverage of immunosuppressive drugs. The Coalition strongly supports legislation introduced in the House by Representatives Canady (R-FL) and Thurman (D-FL), H.R. 1115, and legislation introduced in the Senate by Senator DeWine (R-OH), S. 631. We encourage the Committee to pass this legislation this year.

Roche is a leading research-intensive pharmaceutical company that discovers, develops, manufactures and markets numerous prescription drugs that improve, prolong and save the lives of patients with serious illnesses. Transplantation is among the company's many areas of therapeutic interest. Roche provides a wide range of medications through its marketing and sales subsidiary, Roche Laboratories Inc.

We look forward to working with Congress, the Administration, and the transplant community to increase organ donation rates.

TRANSLIFE
May 5, 1999

The Honorable MICHAEL BILIRAKIS
Chairman
Subcommittee on Health and Environment
Committee on Commerce
U.S. House of Representatives
Room 2125, Rayburn House Office Building
Washington, D.C. 20515-6115

DEAR CONGRESSMAN BILIRAKIS: It was my pleasure to offer testimony on improving the supply of organs for transplantation to your subcommittee on April 15, 1999. I will now take the opportunity to respond to the questions in your letter of April 25, 1999.

Question 1. At the hearing, witnesses testified about numerous state programs to increase organ supplies. If Congress were to move to a national waiting list system, how would that impact existing state policies designed to increase organ supplies?

Response 1. The Florida Statewide Coalition on Donation, a subsidiary of the National Coalition on Donation, was formed to coordinate public education and statewide public service announcements promoting organ donation. The Florida legislature provided some funding for this. Other states are also organizing similar efforts, and like Florida, are funding electronic donor registries within their states. Local OPOs provide the Coalition with the personnel and energy to move forward with these campaigns. Many of the participants are local recipients and donor family members and bring a community effort to the programs. Many of us feel that this community identity does enhance donation and the effort our staffs put forward on its behalf. A movement to a national waiting list could dampen this enthusiasm and lead to fewer donations.

Question 2. Pennsylvania has instituted a program that pays families of organ donors \$300 in state contributions for the donor's funeral expenses, starting this July. What is your opinion on this type of program?

Response 2. The Pennsylvania initiative to contribute \$300 to funeral expenses for the donor explores the issue of financial incentives and I support it as a pilot study addressing this issue. Pilot studies evaluating other incentives such as a paid up insurance policy should also be evaluated. However, a careful analysis of these studies should be done before extending this to the entire donor network. My personal feeling is that financial incentives will be beneficial but only in special subgroups of the population.

Question 3. The proposed HHS regulations to reallocate organs state that "*the OPTN is required to develop equitable allocation policies that provide organs to those with the greatest medical urgency, in accordance with sound medical judgment.*" When President Clinton signed H.R. 3579, the Supplemental Appropriations and Rescissions Act, on May 1, 1998, which extended the public comment period and implementation deadline for the HHS OPTN regulations, he issued a written statement in opposition to extending the comment period on the rule. In stating his reasons for opposing the extension, President Clinton stated that "*The final rule would ensure that organs are allocated to the sickest candidates first.*" What would be the

supply-side effects of a policy where organs were to be allocated to "the sickest candidates first"?

Response 3. UNOS modeling of a "sicker patient first" policy indicates that more organs would be wasted and fewer patients transplanted with poorer overall results. Unfortunately, sicker patients are more likely to die or lose their transplants to post operative complications. My experience in the private practice of medicine for over 25 years, taught me early on that I couldn't "cure" everyone; that, unfortunately, not everyone would ever have equal access to medical care, and one had to learn to deal with "the hand you were dealt". It is, and always will be, an imperfect world.

Question 4. How do we increase the consent rates for families to donate organs? What recommendation would you offer to increase the number of individuals willing to donate their organs?

Response 4. Only hard work and more understanding of the "consent process" will resolve this problem. Fortunately, some scientific approaches are now underway to do so. UNOS has a study to look at several procurement coordinators who have exceptionally high consent rates and to try to identify the characteristics that make them successful. Hopefully, these traits can be transferred to others. The Southeastern Organ Procurement Foundation (SEOPF) has a study evaluating the process (called the trans-theoretical model of behavior modification) that moves someone along the path of making a positive response to donation. We should have some outcome data in 12-18 months.

Question 5. In your estimation, how would the Department of Health and Human Services regulations published April 2, 1998, affect your patients and your ability to provide the highest quality of medical care for them? What impact will this rule have on local access to transplant services nationwide?

Response 5. The Health and Human Services rule that would mandate "broader" sharing would result in increased waiting times for Florida recipients as our patients currently have shorter waiting times when compared to the national averages. This could potentially lead to further deterioration in their health prior to transplantation. Local access to local organs, the optimal transplant situation, would occur less frequently.

Question 6. Could you please explain to the Committee why some areas of the country have much higher rates of organ donation than others?

Response 6. As mentioned in my written testimony, differences in population demographics may play a role in the variations in organ donation in some areas of the country. If an area has a high population of the elderly; of HIV positive individuals or other transmissible diseases (hepatitis, cancer); or minorities, who consent less frequently; donation rates /million population will be low. Some OPOs, though, may be inefficient due to inadequate budgeting for donation activities or have ineffective personnel. We won't know this until we can confidently measure an OPO's true donor potential and compare it to their actual donation rates.

Question 7. As you know, the Department of Health and Human Services regulations have created quite an intense debate about the allocation of organs for transplantation. Some suggest, however, that the debate would be more constructive if it revolved around organ donation instead. What is your opinion?

Response 7. I believe too much energy is being expended on the allocation issues and more needs to be focused on donation. In some OPOs, some transplant programs put little, if any, effort on the donation side. Often the recipient's attending physician is the one most critical of allocation discrepancies but feels "too busy" to get involved in activities to increase donation. That is not to say that allocation issues aren't real, but increasing the supply of donor organs can only solve it.

Question 8. As the number of transplant programs across the country has grown, has the number of transplant procedures grown also? Can you elaborate on the estimated number of procedures which will be performed within the next five years?

Response 8. The opening of new transplant programs does seem to increase donation activity and enthusiasm in those local areas. However, only if actual donation increases, does the number of transplants increase. Otherwise, one simply changes the address for the transplant. We have seen an increase in transplant programs and an increase in transplant procedures this past decade but many factors came into play such as medical advances (splitting organs, unrelated living donors, and expanded donors) that cloud the issue in this relationship. Optimistically, I am hoping for an annual 10% increase in the number of transplants per year over the next 5 years. This is based on increasing the consent rate for donation and improving the efficiency of the various OPOs.

Question 9. In your opinion, does an active local transplant program stimulate organ donation?

Response 9. Yes. It definitely increases local awareness and donation activities as mentioned above. The local procurement staffs may also be more enthusiastic when

they can see the results of their difficult labor expressed in transplant recipients they can both see and touch. After all, they have the most difficult job in this profession.

Question 10. What would you define as an appropriate role for the federal government in the formulation of transplant policy?

Response 10. The federal government, in its role of oversight of the Organ and Transplant Network, should strive to be responsive to the needs of the transplant community. It should assure that a democratic process that includes all members of the transplant community, including recipient and donor families, is utilized in the rule making for the OPTN. It should be in the forefront of passing legislation that will provide adequate funding for the OPTN and its policies as well as demonstrating that the federal government strongly supports organ donation as a proper behavior for all its citizens.

Question 11. Your written testimony stated that there were 4,100 living donors last year, up from 3,905 the previous year and 3,690 the year before that. To what do you ascribe the increase?

Response 11. The increase seen in living donation is related to several factors. The improved results in these kidney recipients versus cadaver transplants have prompted more transplant professionals to emphasize living donation. New surgical techniques for segmental lung and liver transplants have added these organs to the pool in some centers. The expansion of living donation to the biologically unrelated donor (spouses, friends, and now, altruistically motivated strangers) has made the biggest impact; especially in kidney transplants.

Question 12. How long is the recovery for a living donor? Are there new surgical procedures that cut the recovery time? How might this affect supplies of organs?

Response 12. Using the standard donor operation, most donors are out of the hospital in 4-5 days, driving a car in 2-3 weeks and returning to work in 3-6 weeks, depending on the job. New procedures, although a little more risky and difficult, utilizing laproscopic techniques, allow the donor to return home in 48 hours and return to work in 1-2 weeks. As this technique is more broadly utilized, it could attract donors who previously feared the standard procedure and could not afford the costs and the time to donate. Its impact is unknown but could be substantial. It does require extra training and experience for the surgeons to master this technique.

Question 13. How do these patients handle the loss of income in that time period? Are you aware of any companies or insurance policy that would help compensate for this time lost from a job?

Response 13. Most living donors save up their vacation time to cover the time away from work. A small number may have short-term disability plans at work. Often other members of the extended family will contribute financially to help out. Many just suffer the loss and take gratification from their sacrifice. I am not aware of any insurance plans, other than an occasional short-term disability policy, that covers the donor's economic losses. Most don't even cover the medical costs but Medicare or the recipient's insurer then will.

Question 14. In your testimony, you indicated that the current OPO certification process distracts OPOs from actually increasing their organ supplies. Can you elaborate on that comment? Can you recommend an alternative regulatory approach which accurately measures an OPOs performance, yet allows it to maintain its focus on increasing organ supplies?

Response 14. The current certification process with its 2 year cycle, no due process or corrective action plans allowed and based on questionable performance criteria, pressures many OPOs to focus on the certification process itself rather than activities and methods to increase donation. Rather than worrying if their jobs still exist, the personnel can be evaluating and implementing activities that would improve their performance and increase donation.

This past year, HCFA promulgated new rules mandating hospitals to work more closely with OPOs. This development promises to make a significant positive impact on organ donation across the nation. The time has never been better to focus the energies of the organ procurement community and others to increasing organ availability, and not be distracted by certification processes that tend to be more disruptive than supportive or valid for promoting OPO effectiveness and holding them accountable.

The current do-or-die certification process, based on flawed population measures, distracts OPOs forced to compete under an imperfect grading system, with no guarantee of a fair appraisal based on individual improvement in effectiveness. It is impossible for OPOs not to be distracted when their future may largely be determined by events out of their control.

HCFA should currently extend the certification of all OPOs while still monitoring performance using the current standards in order to provide data to OPOs on rel-

ative performance. During the extension, a collaborative industry-government examination of alternative OPO performance measures should be conducted. All parties should agree upon the new process, one similar to that for hospital accreditation. The certification cycle should be 4 years, have a mechanism for responding to and correcting perceived deficiencies, and performance should be measured on the basis of actual donation rates compared to the number of potential donors measured from that service area. This alternative to the current approach would provide a more supportive framework for promoting organ donation and focus OPO efforts more directly on individual improvement.

Question 15. In your oral testimony, you mentioned a study by Dr. Mark Schintzler of Washington University in St. Louis which indicated that every hour of cold ischemic time increases patient costs by \$100 per year. Can you please provide a copy of that study for the record? What implications does this study have for a national system of organ allocation?

Response 15. I have enclosed with this response, a pre-publication copy of Dr. Mark Schintzler's economic analysis of the allocation process, "The Economics of HLA Matching in Cadaveric Renal Transplantation" that he has co-authored with others. His address and phone number are included on the title page. His data indicate that a broader shipping of organs to the "sicker patients" resulting in longer cold ischemic times before the organs are transplanted would be more expensive and produce poorer results. A worse case scenario would occur if no attempt were made to place the organs to the "best" match but simply to the sickest patient regardless of matching. His analysis suggests that the local transplantation of organs allowing shorter cold ischemic times along with an algorithm that would provide for better local matches would be optimal. His analysis only evaluates kidney transplants at this time but some of his principles will likely relate to the other organs also.

Again, I would like to thank you for the privilege of testifying before your Subcommittee and for the opportunity to provide this additional response.

Sincerely,

ROBERT A. METZGER, M.D.
Medical Director

LIFELINK FOUNDATION
May 4, 1999

MICHAEL BILIRAKIS
Chairman
Subcommittee on Health and Environment
U.S. House of Representatives
Committee on Commerce
Room 2125, Rayburn House Office Building
Washington, D.C. 20515-6115

DEAR MR. CHAIRMAN: Thank you for your leadership in addressing the proposed changes to our nation's organ allocation system. We are very appreciative of your efforts. Enclosed are my responses to the questions that resulted from the April 15, 1999 hearing, "Putting Patients First: Increasing Organ Supply for Transplantation." Again, thank you for the opportunity to testify about LifeLink's success.

Question 1. At the hearing, witnesses testified about numerous state programs to increase organ supplies. If Congress were to move to a national waiting list system, how would that impact existing state policies designed to increase organ supplies?

Response. Florida's success has come about because of dedicated work by organ procurement agencies, and by the state in promoting and regulating organ and tissue donation, at great cost to the state and the local organ and tissue donation centers. Florida has enacted numerous statutes to support this work. For example: creating oversight by The Florida Statewide Organ and Tissue Procurement Advisory Board; regulating organ and tissue procurement agencies; establishing an organ donor registry tied to the Department of Motor Vehicles driver license program, which registry can be accessed by hospitals and Organ Procurement Agencies ("OPOs"); enacting an unusual version of the Uniform Anatomical Gift Act, which allows OPOs to approach the courts in cases which do not fit the traditional family model for consent; and other laws. This state work, in partnership with the independent efforts of Florida Hospitals and OPOs, has produced a level of organ donation in Florida that is the highest in the nation. It is also dramatically higher than the level of donation in most other places.

The State of Florida, during the 1998 Legislative Session, passed a law mandating that organs recovered in the State should be offered to transplant centers in Florida with potential recipients who would benefit from the organ first. Essentially, gen-

erous Floridians who consent to organ donation would benefit other Floridians first, keeping them healthy, and getting them back to work when appropriate. If a national waiting list were implemented, preemption of State law would occur, thus ignoring the will of the people of Florida, and sending a precious gift to out-of-state transplant centers which have not worked to develop the donation system in their state. Even so, it is important to note that Florida already supplies a very large number of organs to other states under this current system, a large number of organs which are available for export because of the work of the State and the people of Florida.

Question 2. Pennsylvania has instituted a program that pays families of organ donors \$300 in state contributions for the donor's funeral expenses, starting this July. What is your opinion on this type of program?

Response. We believe this will provide the organ donation and transplantation community an opportunity to view Pennsylvania as a pilot state for the rest of the nation. We will have the opportunity to observe their results, and determine if the stipend for funeral expenses caused an increase in organ donation. If rates of donation increase, we may want to consider a similar initiative. However, we are concerned about the possibility that any incentive system will be viewed by potential donor families as inappropriate when these families consider giving the priceless gift of life. We believe other programs, such as LifeLink's, have been shown to be effective without stipends.

Question 3. What would be the supply-side effects of a policy where organs were to be allocated to "the sickest candidates first?"

Response. The supply-side effects would result from the increased transplant of sicker patients, at great distance from the location of the donation. First, costs will dramatically increase, because of the required private jet transportation of hearts and livers. Second, "warm" time, or the time from organ procurement to implantation, will increase, and thereby decrease the function of the organs. This will also increase costs. The patients at the "top" of the transplant list are very sick, and do not do as well with their transplants as other patients. Therefore, retransplants will increase because very sick patients are more likely to experience rejection of the organ, and transplant hospital stays will increase. Data indicates that a new allocation scheme would substantially increase organ wastage. Also, in States like Florida, the hard work and dramatic success of our local and state organ donation partnership will be diluted by siphoning organs to out-of-state transplant centers. We believe donor families are more likely to donate knowing that the organs will benefit their local community. But we also believe that the staff responsible for acquiring consent and arranging the logistics of organ donation are also motivated by the knowledge that patients in their community are being helped by their hard work. The immediate results are apparent to everyone involved, and give them the greatest incentive to work at their maximum efficiency.

Question 4. How do we increase the consent rates for families to donate organs? What recommendations would you offer to increase the number of individuals willing to donate their organs?

Response. As I stated in my testimony, there are proven key strategies that can help increase organ donation. They include: a simplified referral process; elimination of competition among tissue and eye banks; the use of designated requestors; a focused education program throughout minority communities; a significant hospital development program; and independent organ procurement organizations and transplant centers. However, once consistent referral of all potential donors is achieved, increases can only occur through improved consent. Only persons who have demonstrated substantial skill in appropriate donor family interactions should be allowed to participate in the consent process. Preferably, these persons should be full-time, although that may not be possible.

Nationally, donor consent is at perhaps 48%. LifeLink's consent rate is 75% if hospital approaches to donor families are included, above 85% if they are not. The national "conversion" rate (medically suitable referrals which become donors) is perhaps 40%. LifeLink's conversion rate is 58%. We believe this increased conversion rate, and the increased consent rate, flows from having extremely skilled "requestors", and very motivated employees involved in every other aspect of donation.

Question 5. In your estimation, how would the Department of Health and Human Services regulations published April 2, 1998 affect your patients and your ability to provide the quality of medical care for them? What impact will this rule have on local access to transplant services nationwide?

Response. We believe that our local transplant center patients will be significantly and negatively impacted, as will the vast majority of the country's 120 liver transplant centers. Donated livers will be sent from Florida to a half dozen urban regional transplant centers—none of which are in the southeast. Our community will

be deprived of this life-saving resource, a resource which our local citizens and the community have developed together. Highly skilled doctors and nurses will no longer perform the same number of transplants. Local centers may be forced to close their doors.

In addition, access for low-income patients may be decreased. Medicaid patients may be unable to obtain transplants outside their home state, and other patient families may not be able to accompany their loved one to support them at a faraway transplant center. Also, organ donation will be affected. Many donor families have stated that a key factor in their decision to donate was the knowledge that they would be helping someone within their community.

Eliminating this motivation may substantially reduce voluntary organ donation nationwide.

Question 6. Could you please explain to the Committee why some areas of the country have much higher rates of organ donation than others?

Response. Some organ procurement organizations, such as LifeLink, have invested the resources necessary to educate hospital staff; nurses, physicians, and administrators, about donation so that the referrals will be provided to the organ procurement organization in a timely and well received manner. For example, LifeLink has 21 full-time persons working in the State of Georgia alone in hospital and minority education.

Public education programs have also been established to provide an overall awareness about the need for organ donors. Quite simply, some organizations have not invested the necessary resources to make an impact on the donor shortage. In addition, some transplant centers have grown their list so heavily that the rate of donation in those communities can never serve the needs of those patients. It is important to note that this phenomena is in part a result of managed care programs forcing patients to be listed at transplant centers because of favorable contracts. These lists become unmanageably long, and out strip the supply of local organs.

Question 7. As you know, the Department of Health and Human Services regulations have created quite an intense debate about the allocation of organs for transplantation. Some suggest, however, that the debate would be more constructive if it revolved around organ donation instead. What is your opinion?

Response. We believe increasing organ donation is the number one challenge we face, and presenters at the April 15th hearing provided constructive methods for accomplishing that. There is, if current numbers are accurate, the potential for actually acquiring up to 4,000 more organ donors each year nationally, by increasing consent rates to 75-80%, acquiring virtually all suitable donor referrals, and maximizing the donor potential from those referrals. At over three organs per donor, 12,000 more organs each year could reduce the existing list to a manageable number soon. However, until this year's approximately 5% increase in organ donors, the national figures have remained virtually stagnant.

Question 8. As the number of transplant programs across the country has grown, has the number of transplant procedures grown also? Can you elaborate on the estimated number of procedures that will be performed within the next five years?

Response. Yes, the number of transplant procedures has grown, but this number is dwarfed by the increase in the patient waiting list. The increase in local transplant centers has more equitably spread the number of procedures from large urban transplant centers to local centers, whose surgeons previously trained at the large urban centers. Access to transplant centers in the local community allows patients to receive care close to home, with the support of family and friends. This is a positive phenomenon. However, without an increase in the number of available organ donors, the number of transplants cannot dramatically increase. The proposed change in allocation policy can only redistribute organs and change the addresses of those patients who do not receive organs and will die as a result.

Only an increase in organ donation can save lives, and that is where we should be directing our national efforts.

Question 9. In your opinion, does an active local transplant program stimulate organ donation?

Response. Absolutely! The sense of identification with local patients, and with the patients across an OPO's home state, is integral to the success of an organ donor program. Of course OPO staff want to help any patient in need, but the drive that is needed to perform this kind of heart-wrenching work day after day is further fueled by knowing the names and identities of those local patients who wait. The energy to take all appropriate steps to locate organ donors is increased when the individual efforts of these employees sometimes save the life of someone the coordinator knows. Also, active local transplant centers increase awareness in the community about organ donation and educate the public about organ donation by their very presence.

Question 10. What would you define as an appropriate role for the federal, government in the formulation of transplant policy?

Response. The Federal government should ensure that proper minimal performance standards are set, and met, and that organizations which do not meet these standards are removed. However, when it comes to policies regarding distribution of organs, the Federal Government should allow the scientific and medical community, with proper non-political oversight, to enact and enforce rules designed to maximize organ usage and patient survival. This process is a fast moving, fluid one, as is transplantation itself, and is not the appropriate place for regulation by the law-making process, which is slow and subject to political influence.

Question 11. What are some of the key elements in helping LifeLink achieve recognition for the highest number of transplantable organs in the nation? What are some of your practices in identification and organ donation that other organ procurement organizations are not using?

Response. The key elements that have helped LifeLink achieve the highest rate in the nation include: a simplified referral process; the elimination of competition among tissue and eye banks; the use of specially trained designated requestors; a focus on the minority community; a significant hospital development program; and an independence from the transplant centers we serve.

Many organ procurement organizations have not invested in the hospital development program, or helped to eliminate competition among eye and tissue banks. Many OPO executive directors, when asked why they have not implemented and fully funded hospital development programs, or designated requestor or minority education/requestor programs, respond that their board members would not approve of the necessary increase in charges. Under the current system, many, if not most, of an OPO's board members are transplant center representatives, and have a conflict of interest when such issues are raised.

Recognizing this problem, LifeLink is structured to meet government advisory board composition criteria, while keeping its governing board representative of the community.

Please contact me if additional information is required. It has been a pleasure working with your staff members Todd Tuten and Mark Wheat.

Sincerely,

JOHN R. CAMPBELL, P.A., J.D.
Senior Vice President/General Counsel

NATIONAL KIDNEY FOUNDATION
OFFICE OF SCIENTIFIC AND PUBLIC POLICY
May 5, 1999

The Honorable MICHAEL BILIRAKIS
Chairman, Subcommittee on Health and Environment
U.S. House of Representatives
Committee on Commerce
Room 2125, Rayburn House Office Building
Washington, DC 20515-6115

DEAR CHAIRMAN BILIRAKIS: Thank you for your letter of April 21, 1999. On behalf of the National Kidney Foundation (NKF) I wish to express again our appreciation for the privilege of presenting the NKF perspective on "Putting Patients First: Increasing Organ Supply for Transplantation," at the Subcommittee hearing on April 15, 1999. We also appreciate the opportunity for additional input on the issues which were raised during the hearing by responding to the questions posed in your recent letter.

Question 1. At the hearing, witnesses testified about numerous state programs to increase organ supplies. If Congress were to move to a national waiting list system, how would that impact existing state policies designed to increase organ supplies?

Response. We are concerned that states may have less incentive to continue to develop innovative programs to increase the supply of organs available for transplantation if Congress were to move to a national waiting list system. Furthermore, state legislatures could be less likely to support funding for such innovative programs if there were a national waiting list.

Question 2. Pennsylvania has instituted a program that pays families of organ donors \$300 in state contributions for the donor's funeral expenses, starting this July. What is your opinion on this type of program?

Response. The National Kidney Foundation has long called for demonstration projects to determine the impact of programs which would assist donor families in

paying for funeral or burial expenses, based upon the recommendations of our consensus conference, "Controversies in Organ Donation," which was held in 1991.

Question 3. The proposed HHS regulations to reallocate organs state that "the OPTN is required to develop equitable allocation policies that provide organs to those with the greatest medical urgency, in accordance with sound medical judgement." When President Clinton signed H.R. 3579, the Supplemental Appropriations and Rescissions Act, on May 1, 1998, which extended the public comment period and implementation deadline for the HHS OPTN regulations, he issued a written statement in opposition to extending the comment period on the rule. In stating his reasons for opposing the extension, President Clinton stated that "The final rule would ensure that organs are allocated to the sickest candidates first." What would be the supply-side effects of a policy where organs were to be allocated to "the sickest candidates first"?

Response. We believe that less patients would receive liver transplants if the OPTN were required to develop policies where organs are allocated to the sickest candidates first. Such candidates are likely to have poor outcomes and require repeat transplants, thus reducing the number of organs available for other candidates. Furthermore, NYF has maintained that a "sickest first" policy should not be applied to renal transplantation because of the availability of dialysis as an alternative therapy.

Question 4. How do we increase the consent rates for families to donate organs? What recommendations would you offer to increase the number of individuals willing to donate their organs?

Response. To respond to this question, it is necessary to differentiate between cadaveric organ donation and living organ donation.

The experience in Pennsylvania indicates that cadaveric organ donation could be increased through implementation of the "required referral" provision in the new HCFA Conditions of Participation for hospitals. This puts individuals trained in the consent process at the bedside of potential donors. Registries which track individuals who have executed organ donation directives might also be helpful in the consent process since they give the donor family indisputable evidence of the wishes of the decedent. As indicated in our testimony, removing the disincentives for living donation, including financial disincentives, could increase the number of individuals who are willing to donate.

Question 5. In your estimation, how would the Department of Health and Human Services regulations published April 2, 1998, affect your patients and your ability to provide the highest quality of medical care for them? What impact will this rule have on local access to transplant services nationwide?

Response. We are concerned that the April 2, 1998 regulations have politicized the organ donation/organ allocation process since they give the DHHS Secretary veto power over OPTN policy. Transplantation should be based upon medical science, not politics. We are concerned that the rule may cause some local transplant centers to close and that would make it difficult for low income transplant candidates to receive a transplant. Such candidates may not be able to afford to travel to distant transplant centers for evaluation, the transplant itself and post-operative care and testing.

Question 6. Could you please explain to the Committee why some areas of the country have much higher rates of organ donation than others?

Response. There are many factors that influence organ donor rates in different parts of the country. The ethnic/racial/cultural mix of the community where individual organ procurement organizations operate is an important variable. Some groups have traditionally been more likely to donate than others. Also, a high incidence/prevalence of HIV infection in a community is a contraindication for organ donation. Finally, there is variance in the performance of the organ procurement agencies themselves.

Question 7. As you know, the Department of Health and Human Services regulations have created quite an intense debate about the allocation of organs for transplantation. Some suggest, however, that the debate would be more constructive if it revolved around organ donation instead. What is your opinion?

Response. The National Kidney Foundation firmly believes that the focus of the debate in Congress should move from organ allocation to organ donation and we are very pleased that your Subcommittee has held a hearing to begin that process. In particular, provisions to increase the supply of organs available for transplantation should be included in the re-authorization of the National Organ Transplant Act of 1984. A change in allocation policy fails to address the larger issue-the growing transplant waiting list.

Question 8. As the number of transplant programs across the country has grown, has the number of transplant procedures grown also? Can you elaborate on the estimated number of procedures which will be performed within the next five years?

Response. Extrapolating from the current experience, Thomas Gonwa, M.D., chairman of the NKF Council on Transplantation, provided the following estimates for the number of transplants which will be performed in the next five years:

Kidney	60,000-80,000
Liver	30,000-35,000
Heart	10,000-15,000
Lung	5,000
Kidney/Pancreas	4,000

The number of those procedures will be largely influenced by trends in organ donation. However, developments in science and changes in policy also have a role to play. Science can contribute to the availability of organs for transplantation by finding new ways to prevent graft loss and thus reduce the need for second and third transplants. Another example of the role of science is in split liver and partial lung transplants which multiply the use of organs which are donated. The promise of required referral is that it could increase organ donation by 20%. *Finally, reimbursement policy has a role to play to the extent that extending the period of time during which Medicare pays for anti-rejection drugs could reduce the need for second and third transplants. For this reason, the NKF is a strong advocate of H.R. 1115 and S. 631, legislation that would eliminate the current 36-month time limitation for Medicare coverage of immunosuppressive medications for transplant recipients.*

Question 9. In your opinion, does an active local transplant program stimulate organ donation?

Response. It is the opinion of the National Kidney Foundation that an active local transplant program stimulates organ donation.

Question 10. What would you define as an appropriate role for the federal government in the formulation of transplant policy?

Response. The federal government should assist in the formulation of transplant policy by facilitating and funding demonstration projects as well as by supporting basic and clinical research on transplantation. It should also establish reimbursement policy (for Medicare and Medicaid and as a model for private third party payers) which a) is consistent with transplant science, b) promotes the welfare of transplant candidates and transplant recipients and c) maximizes utilization of organs which are donated.

Question 11. I was very pleased to learn that the number of living organ donors increased by 95% over the period from 1988 to 1996. What accounts for this increase in donations? How can we continue to replicate its success?

Response. The number of living donations has grown as transplant centers have developed programs to tap the potential of living transplantation. This could further increase as more centers are encouraged to develop such programs and guidelines are developed to improve the information provided to potential donors. Additionally, the potential of living organ donation could be enhanced by protocols permitting emotionally related donation and paired donation. As noted above, eliminating the financial disincentives for living donation would help to maintain the momentum.

As stated in our testimony for the hearing, living organ donation is a priority for the National Kidney Foundation. In the coming year NKF will sponsor a consensus conference to explore ways to increase living organ donation and better serve living organ donors.

Question 12. You indicated that a survey conducted by the National Kidney Foundation found that a majority of respondents indicated that they would prefer that donated organs be used locally. Could you provide the Committee a copy of the survey for the record? In your opinion, how would a national waiting list affect donations?

Response. By way of background you should know that the NKF is a federation of 52 local kidney foundations, known as "Affiliates," and that the NKF umbrella includes three "constituent" councils (the National Donor Family Council, the Patient and Family Council and the transaction Council), seven "scientific" councils and three "professional" councils (among the latter are the Council on Transplantation and the Council of Nephrology Social Workers). The 4,229 constituents of our National Donor Family Council have had the personal experience of giving the "Gift of Life" and the 3,317 members of the NKF transaction Council have benefitted from a life-saving organ transplant. In all, NKF represents 30,000 lay and professional volunteers from every walk of life and every part of the United States.

In response to the April 2, 1998 regulations, three conference calls were convened to survey the NKF constituent councils concerning the new policy during the week

of April 13, 1998. The views of the members of the Executive Committees of the National Donor Family Council, the transaction Council and the Patient and Family Council, respectively, were elicited during those conference calls. Throughout the month of May 1998, NKF sought input on the regulations from our Affiliates. A questionnaire was distributed by fax and a second copy of that instrument was mailed to every Affiliate office.

The National Kidney Foundation is grateful to be able to serve as a resource as Congress debates the future of organ donation and transplantation. We have helped to shape public policy in this area for more than 30 years and stand ready to provide any additional information or assistance that the subcommittee might find useful at this point in time.

Sincerely,

JOSEPH L. BRAND
Chairman

RESPONSES FOR THE RECORD OF DR. ROBERT HIGGINS, DIRECTOR OF THORACIC
ORGAN TRANSPLANTATION, HENRY FORD HOSPITAL

Question 1. At the hearing, witnesses testified about numerous state programs to increase organ supplies. If Congress were to move to a national waiting list system, how would that impact existing state policies designed to increase organ supplies?

Response 1. A national waiting list with no preference for local patients would negate the incentive for potential donors to donate an organ that could benefit someone in their local community, state or region. OPO, hospital and medical personnel feel strongly that donor families are impacted by first-hand accounts of organ donation success stories and local media coverage about transplant recipients. Organ donation is a local phenomenon and as such is impacted by cultural and religious beliefs that are difficult to understand or respond to on a "one size fits all" basis.

Issues related to death and dying have traditionally been the responsibility of the states and issues related to organ donation and disposition are covered under state law. Under the Uniform Anatomical Gift Act, which is the model donation statute for all states, responsibility for organ donation efforts such as drivers license check off, the legal definition of who is a donor and who is a donee, as well as other legal issues are addressed. A national system would break up these traditional responsibilities and relationships that support organ donation in the states as defined in the Uniform Anatomical Gift Act and would essentially be a federal over-reach into an area which has traditionally been the prerogative of the states.

Question 2. Pennsylvania has instituted a program that pays families of organ donors \$300 in state contributions for the donor's funeral expenses, starting this July. What is your opinion on this type of program?

Response 2. The issue of financial incentives for organ donation is a complex moral and ethical question which has been debated for some time. As it stands now, economic incentives for organ donation are illegal based upon the National Organ Transplantation Act of 1984 (Public Law 98-507).

We question the advisability of tying financial incentives to a system which has been based upon altruism and voluntary donations of organs. Families are already apprehensive about donating a loved one's organs due to a lack of information, superstitions, religious beliefs, and culturally driven attitudes about death, often mixed with a feeling that the hospital, health plan, or medical staff may not perform all possible interventions on the patient so that the organs can be used elsewhere. The "who", "how", and "why" of donating organs are unclear to many, and adding a new dimension with monetary incentives may cloud or create even more suspicion during the sensitive decision making period by family members.

The potential for coercive economic incentives that may undercut the altruistic nature of donation and create questionable motivation for donation, in particular for those who are in financial need, is a significant concern.

Thus, prior to formalizing any kind of system of remuneration, diligent consultation with the medical profession, medical ethicists and legal experts should be secured. In addition, we are a society that is grappling with issues of assisted suicide and the right of patients and families to terminate treatment, all of which introduce opportunities to make tragic mistakes in decisions relating to financial incentives for organ donations.

If Congress or state governments decide to proceed with even small monetary incentives, such as payment for funeral costs, we strongly recommend close supervision, public disclosure and tight controls over the way the program is implemented. Even small amounts begin the danger of starting down a slippery slope that can lead to the dangers of a payment system for organs. We acknowledge, how-

ever, that clearly defined financial incentives such a “rewarded gifting” in the form of modest sums of money paid to a family to defray costs of funeral expenses may benefit individual transplant recipients and the society at large. These kinds of initiatives, of course, would have to be carefully delineated, so as not to be construed as a payment system for organs.

Question 3. The proposed HHS regulations to reallocate organs state that “the OPTN is required to develop equitable allocation policies that provide organs to those with the greatest medical urgency, in accordance with sound medical judgment.” When President Clinton signed H.R. 3579, the Supplemental Appropriations and Rescissions Act, on May 1, 1998, which extended the public comment period and implementation deadline for the HHS OPTN regulations, he issued a written statement in opposition to extending the comment period on the rule. In stating his reasons for opposing the extension, President Clinton stated that “The final rule would ensure that organs are allocated to the sickest candidates first.” What would be the supply-side effects of a policy where organs were to be allocated to “the sickest candidates first”?

Response 3. A “sickest first” policy would increase the number of re-transplants as more patients experience graft rejection, and thus reduce the number of organs available for transplantation overall. Patients would have to become “sicker” in order to receive a transplant, thus reducing their chance for survival. This would be completely counter-productive and result in increased cost with reduced success.

Question 4. How do we increase the consent rates for families to donate organs? What recommendation would you offer to increase the number of individuals willing to donate their organs?

Response 4. The key to overcoming donor families reluctance to consent is twofold: 1) better educational programs to increase the knowledge about organ donation and transplantation including involving religious and community leaders, and 2) a “best practices” approach in terms of asking for family consent that could be implemented in every hospital. Mandatory referral by the hospital to the OPO is also an important part of increasing organ donation.

Question 5. In your estimation, how would the Department of Health and Human Services regulations published April 2, 1998, affect your patients and your ability to provide the highest quality of medical care for them? What impact will this rule have on local access to transplant services nationwide?

Response 5. A national list coupled with a sickest first policy would make it all but impossible for my patients and in particular patients everywhere that are poor or minority patients, to receive a transplant. From a physician’s point of view, without available organs, there is nothing I can do to help my patients over the longer term. If the rule were in effect today, the federal government would essentially be denying the benefits of organ transplantation to a broader number of patients.

Question 6. Could you please explain to the Committee why some areas of the country have much higher rates of organ donation than others?

Response 6. Many factors come into play. Areas that do not have a transplant center generally do not have a well-developed organ donation infrastructure and the associated outreach programs in place. In some areas, there is clearly a need for increased efforts while in other areas, because of population, economic or cultural reasons, efforts to increase donation will have a limited effect.

Question 7. As you know, the Department of Health and Human Services regulations have created quite an intense debate about the allocation of organs for transplantation. Some suggest, however, that the debate would be more constructive if it revolved around organ donation instead. What is your opinion?

Response 7. I absolutely agree. The real solution to the problem is to focus our efforts on ways to increase organ donation. We are currently reaching only about 35% of potential donors and getting consent from only about 50% of those we do reach. If we increased the organ donation rate for livers from 21 donors per million, which is the current average, to 30 donors per million, the waiting time for a liver transplant would be less than 20 days for all patients in all regions of the country.

A recent Associated Press analysis of the 63 organ procurement organizations across the country concluded that 2000 more transplants could be performed each year if each below-average organ bank performed up to the median level.

Question 8. As the number of transplant programs across the country has grown, has the number of transplant procedures grown also? Can you elaborate on the estimated number of procedures which will be performed within the next five years?

Response 8. As the number of transplant programs across the country has grown, there has been a corresponding increase in the number of transplant procedures. Though there has been no extensive scientific study undertaken to determine this, UNOS data clearly shows that between 1988 and 1995, the number of liver transplant centers in the U.S. grew from 70 to 119, a 70% increase. During the same

time period, as transplantation became a reality for many without the means to travel, the number of liver transplants grew from 1,713 to 3,923, an increase of 129%. Transplantation is a reality today for more people than ever before, and we must recognize that it has evolved in the context of the consensus-oriented process developed by the OPTN—not by a federal directive.

Question 9. In your opinion, does an active local transplant program stimulate organ donation?

Response 9. In my opinion, an active local transplant program does indeed stimulate organ donation. My experience has taught me that when a community can relate to the miracle of transplantation, often through knowing someone or reading about someone whose life was saved, increased awareness and participation are the result. If transplantation were a phenomenon that “happened somewhere else,” local communities would have a more difficult time engaging people in the process of organ donation. People must be able to feel the positive impact of transplantation in their community in order to achieve the maximum level of participation and awareness.

Question 10. What would you define as an appropriate role for the federal government in the formulation of transplant policy?

Response 10. The appropriate role for the federal government in the formulation of transplant policy has been clearly defined by the National Organ Transplant Act of 1984 (NOTA). This is the position with which I am aligned. NOTA very explicitly states that the OPTN, which consists of not only surgeons, but patients, donor families, and OPO representatives, shall be primarily responsible for the development and implementation of sound transplant policies, while the Secretary of the Department of Health and Human Services exists in an oversight capacity. The appropriate role, therefore, is for the federal government to ensure the implementation of sound transplant policy *as developed by the medical experts and consumers involved in transplantation every day*. The federal government should not be in the position of proposing transplant policy. The transplant community feels very strongly that we—the surgeons, donors, donor families, patients, and OPOs—must continue to develop transplant policy in a consensus-driven process that is able to respond to the latest advances in medical technology, while simultaneously ensuring the maximum level of access to transplantation for all patients.

Question 11. Why have donation rates among minorities been so low?

Response 11. Donation rates among minorities have been low for several reasons. The most glaring shortfall has been in the African-American population, where donation rates had been 7% only a few years ago. It is now running closer to 15% which is commensurate with the percentage of African-Americans in the general population. Clearly we have begun making progress, but there remains significant room for improvement. In my opinion, this problem stems mainly from the issue of access to transplantation and other medical services. Minority populations have historically suffered from inadequate access to quality medical care. This has bred a distrust of the “medical establishment” as minorities tend to view medicine with suspicion and apprehension. This has resulted in a hesitancy to donate, with patients believing their organs will not be utilized to benefit minority patients, but go to “white” patients who are able to afford them. There is also a fear that the “medical establishment” will not do everything possible to save their life if they have indicated they intend to donate their organs. These concerns are not founded, and must be countered with outreach efforts in minority communities.

There have also been religious concerns raised, with patients expressing the need to “go to heaven whole.” Community churches must undertake efforts to ensure patients are educated about the benefits of transplantation.

Question 12. What are some of the strategies to increase organ donation that have worked best in minority communities?

Response 12. MOTTEP—The Minority Organ Tissue Transplantation Education Program, headed by Dr. Clive Callender, has made tremendous inroads into this problem. The program is grassroots and seeks to educate the public not only about organ and tissue donation but also health care issue as well (e.g., avoiding salt and fried foods, regular checkups, etc)

This program has been instrumental in raising organ donation rates among minorities in or region. Moreover, I believe it has been a big reason why donation rates have increased nationally.

Also, the use of minority coordinators who speak with potential donor families has improved consent rates. This strategy helps assuage concerns that the “establishment” is only after their loved one’s organs and allows the family to grieve with someone of the same ethnicity who would potentially understand their concerns better.

The MOTTEP paradigm could and should be used nationally. Their philosophy can be easily transferred to the general public; however, it will take substantial backing by the government to fund these education programs on a national basis. MOTTEP works because people go to churches, schools, malls, and wherever people might be. It is very labor intensive but it is the only way to answer questions. Having advertisements with Michael Jordan are well intentioned but unless people can see the direct benefits and ask questions first hand, no major dent in the donation rate will be seen.

Question 13. In your testimony, you discussed the increasing prevalence of living organ donations. How would you reassure a potential living donor about the safety and viability of the procedure?

Response 13. The physician or staff involved with the procedure are typically responsible for educating and explaining the risk of any surgical procedure. It is incumbent upon the physician to fully disclose the status of living donor transplantation. For example, data should be shared related to patient risk and outcomes so that patients can make informed decisions about whether to proceed.

AMERICAN SOCIETY OF TRANSPLANT SURGEONS

May 5, 1999

The Honorable MICHAEL BILIRAKIS
Chairman
Subcommittee on Health and Environment
U.S. House of Representatives
Committee on Commerce
Room 2125, Rayburn House Office Building
Washington, DC 20515-6115

DEAR CHAIRMAN BILIRAKIS: It was an honor to appear as a witness on April 15, 1999 before the Subcommittee on Health and Environment under your leadership. As you know, I represent the American Society of Transplant Surgeons (ASTS) and offered our testimony on increasing the organ supply for transplantation. The following are follow-up answers to the questions you posed in your letter to me of April 21, 1999.

Question 1. At the hearing, witnesses testified about numerous state programs to increase organ supplies. If Congress were to move to a national waiting list system, how would that impact existing state policies designed to increase organ supplies?

Answer. First of all, the term "national waiting list" is a misnomer in that it no longer characterizes what is being proposed by the Department of Health and Human Services (DHHS). All parties including DHHS now appear to recognize that a unified national allocation scheme—which routes organs to the next name on the list without regard to where the organ was retrieved or where the patient is located—is not a practical possibility, particularly given the importance of minimizing cold ischemic time, at the current state of organ preservation technology.

But DHHS certainly is proposing to move away from the current system of allocation to a system of broader geographic sharing. We acknowledge that certain artificial boundaries have been established in the designation of UNOS regions, and in the creation of Organ Procurement Organization (OPO) territories (the latter, approved and designated by the Health Care Finance Administration), that have created inequities in distribution in *certain areas of this country*. In several cases, reliance on rivers, state lines, and even city limits to define distribution areas aggravates some inequities. These should be specifically addressed and remedied. But there certainly are no persistent glaring national injustices that necessitate the type of radical change of distribution policies proposed by DHHS, which we believe would have a strong negative impact on states that have more effective organ donor programs.

For instance, in our own state of Florida, population clusters are fairly evenly geographically distributed and far enough away from the neighboring states of Georgia and Alabama that state boundaries cannot play an adverse role in general in distribution. If one looks at New York and New Jersey, the perspective is entirely different. Louisiana also has population centers in general away from the population centers with transplant programs of other states. The case is similar in California, but contrasts to the situation presented in some state pairs such as Wisconsin and Illinois.

The complexity increases when one considers that, as mentioned in a succeeding question, some states indeed have more effective organ donor programs (as we are blessed with here in Florida) than other states. There is no simple explanation or solution to this phenomenon. Pockets of our populace still do not have cadaver organ

donation in their cultural mores, such as Orientals in population centers on the West Coast. This is also true in some cities where massive population growth has been fueled by refugees from countries in which organ donation is less-advanced, such as those from Central America, Mexico, and the Caribbean.

With this background, the answer to your question is that moving to a national list would indeed have a negative impact on organ donation in a number of states. We would hope Congress would recognize that the current system—constantly modified by experts on the preservation of specific organs and their transplantation—has been most effective in the equitable distribution of all organs for the years of its existence. It recognizes that organ donation to not-fully-appreciated extent is a local phenomenon, for a variety of social as well as geographic reasons. OPOs function most effectively when driven by their transplant surgeons and by the needs of their local patients. Such is the motivation that breeds success in organ retrieval. The current system may need further fine-tuning, but it is NOT broken.

Question 2. Pennsylvania has instituted a program that pays families of organ donors \$300 in state contributions for the donor's funeral expenses starting this July. What is your opinion on this type of program?

Answer. I personally see no ethical issue. Other incentives might be even serve as more of a motivation to increase donation, but I view this as an interesting effort and we will obviously be interested to see if it has an impact on the donation rate.

Question 3. The proposed HHS regulations to reallocate organs state that "the OPTN is required to develop equitable allocation policies that provide organs to those with the greatest medical urgency, in accordance with sound medical judgment." When President Clinton signed H.R. 3579, the Supplemental Appropriations and Rescissions Act, on May 1, 1998, which extended the public comment period and implementation deadline for the HHS OPTN regulations, he issued a written statement in opposition to extending the comment period on the rule. In stating his reasons for opposing the extension, President Clinton stated that "The final rule would ensure that organs are allocated to the sickest candidates first." What would be the supply-side effects of a policy where organs were to be allocated to "the sickest candidates first"?

Answer: The ASTS has made it clear that we believe the impact of such a "sickest first" policy would be contrary to our goal of insuring that the precious organs presently available provide the maximum benefit to the maximum number of Americans in an equitable fashion. This point was made in testimony presented at two previous Congressional hearings by Dr. Ronald W. Busuttil, President-elect of the Society and director of the world's most active liver transplant center in UCLA, and I am submitting copies of his testimony with this response. I also include a copy of our written testimony to the Institute of Medicine, presented by Dr. Busuttil on April 16th, which expands on these points.

Unfortunately, critical care medicine and vital organ transplantation is not an exact science. That is why a significant number of Status 3 liver patients, those thought to be the least sick, die while in that status. We urge the Congress to leave decisions of this kind in the hands of the medical professionals—who battle these life-and-death issues with their patients every day—and not permit them to be imposed by governmental authority far from the trenches where life and death is played out.

The simple answer is that there are some changes that must evolve in the distribution of life-saving organs for transplantation, as they have evolved in the past. This can be accomplished with the help of the federal government, but not with the implementation of a radically new OPTN rule which with its current inferences, language, and preamble has resulted in sound-bites such as "sickest patients first."

Question 4. How do we increase the consent rates for families to donate organs? What recommendation would you offer to increase the number of individuals willing to donate their organs?

Answer: For one thing, the ASTS itself has launched a very logical public educational campaign—The First Family Pledge Campaign—that has as a general concept (to be accepted by the general public, as it has been by our congressional leaders) discussion of organ donation as a family event. I include information on this campaign and express our gratitude to you for your participation and your leadership in it.

There are some additional simple points that should be stated relative to public support for organ donation. The acceptance of seatbelts by the American public was a generation in coming. I, myself, must confess that I did not use them until five years ago when shamed into doing so by my five year-old grandchild. He learned it in school. The importance of organ and tissue donation must be ingrained into our American culture from early grade school onward, together with the Pledge of Allegiance and the multiplication tables. Organ donation must come to be viewed

as part of our American way of life. The First Family Pledge is really no more than an extension of the Golden Rule.

There are additionally several other specific operational initiatives that I refer to in my testimony being implemented by the ASTS and its co-partners this year. These initiatives would be helped by some minimal underwriting from either HCFA or HRSA. I would be most happy to discuss them in more detail with you or your staff as well.

Question 5. In your estimation, how would the Department of Health and Human Services regulations published April 2, 1998, affect your patients and your ability to provide the highest quality of medical care for them? What impact will this rule have on local access to transplant services nationwide?

Answer: In general the rule as *currently* written will impact negatively upon patients nationwide. I personally work in a large transplant center, one of the five largest in the world, and am proud of our record over the years. I also have been proud of our organ procurement agency, the University of Miami OPO. This has repeatedly over the years had one of the most enviable records nation- and worldwide in organ retrieval for life-saving transplantation. This is due to our local OPO Director, Les Olson, with whom I have had the privilege of working for 30 years, first in Minnesota, and then for over 20 years in South Florida. Please make no mistake. Organ donation is a local phenomenon dependant on the expertise of professional personnel. That also accounts for the great records in organ retrieval of Lifelink in West Florida, for Translife in Central Florida, and for the University of Florida OPOs. How could those who drafted the OPTN rule not acknowledge this? Some of the language in the OPTN rule also will have a negative impact on local access to service. I can expand on this, but I refer you to comments already made by our ASTS (enclosed). It is also worth noting that the vast majority of the written comments on the rule, collected by DHHS and not yet described by the Department, are understood to have been negative.

Question 6. Could you please explain to the Committee why some areas of the country have much higher rates of organ donation than others?

Answer: In brief, the variables are: (1) The expertise of OPO personnel and their motivation; (2) Cultural and ethnic pockets of population with a more negative view of the process; (3) The failure to appreciate the extent to which the driving force attaining high rates of organ donation are the transplant professionals involved in the act of transplantation, led by transplant surgeons.

Question 7. As you know, the Department of Health and Human Services regulations have created quite an intense debate about the allocation of organs for transplantation. Some suggest, however, that the debate would be more constructive if it revolved around organ donation instead. What is your opinion?

Answer: I agree totally with this statement. The problem of allocation will not be "solved" until we increase the organ donation rate in a way that allows any patient in need of an organ to benefit from this new chance at life. The government certainly should be focusing its attention on increasing public support for donation, and leaving the triage of complex medical conditions to the "docs," where it belongs.

Question 8. As the number of transplant programs across the country has grown, has the number of transplant procedures grown also? Can you elaborate on the estimated number of procedures which will be performed within the next five years?

Answer: The number of transplant procedures has certainly grown, and will continue to grow. The estimated number to be performed in the next five years is truly limited by the availability of donor organs. The number of potential recipients has grown, conservatively, by about 10% per year for the last three or four years, and could continue to do so for the next five years. In fact, when one considers the future need for liver transplantation in light of the epidemic of hepatitis C, which is now occurring in the United States, an even greater number of transplants may be required. It has been estimated that within 10 years there will be a 61 per cent increase in cirrhosis, and a 529 per cent increase in the need for liver transplantation due to Hepatitis C. Furthermore, the technology of improved organ preservation, xenografting, and even organ cloning may well impact these numbers within the first decade of the new millennium.

Question 9. In your opinion, does an active local transplant program stimulate organ donation?

Answer: Yes, for reasons previously described, organ donation is very much driven by active, aggressive, and respected local transplant surgeons and other expert professionals, and vice versa.

Question 10. What would you define as an appropriate role for the federal government in the formulation of transplant policy?

Answer: The federal government should assist the professionals by providing enforcement of the regulations generated by the OPTN, UNOS. The federal govern-

ment has the responsibility for oversight of the OPTN, and the implementation of NOTA. NOTA *begs* to be reauthorized with the firm principle clearly established that *the final responsibility for the life and death medical decisions inherent in organ allocation and distribution should repose with medical professionals*, and be made on the basis of scientific fact and not potential political influence. We, as physicians, hold this task as the highest motivational force in our lives and our professional careers. We took an oath. The final responsibility for medical decisions should lie with the medical community, and not with the Secretary of Health and Human Services. That is what this is all about.

Question 11. Can you discuss the progress of efforts to successfully preserve transplantable organs outside the body?

Answer: Progress in this particular field may not appear to be steady, and by no means is it expanding geometrically as in other areas of transplantation. It is one of our most limiting variables in organ availability. However, strides are being made in cryopreservation of cells, tissues, and even complex organs that deal with the susceptibility of subcellular structures to crystallization, so as to freeze them for prolonged periods. Also, tissue culture technology has seen more remarkable advances with the identification and molecular generation of growth factors for certain types of tissue, and the maintenance of cells, tissues and even of organs *ex vivo*, possibly even of their generation in tissue culture. The practical implementation of such technology is difficult to predict. But, there are indicators that significant applicable progress will be made in the next ten years, provided the funds for underwriting the research continue to be available.

Question 12. In your testimony, you mentioned initiatives underway to increase consent rates in Great Britain and Spain. Can you elaborate on those approaches and what we can learn from them?

Answer: The ASTS has already performed site visits to the programs in these countries working with individual OPOS, and is working in partnership with the American Organization of Procurement Organizations (AOPO) to implement that which we have learned.

1.) In the national initiative from Great Britain, the improved identification and maintenance of suitable donors for heart and lung transplantation has the potential for doubling the number of donors available for such transplants in our country. This involves new intensive care monitoring techniques that are being described in a grant application to the National Heart, Lung and Blood Institute of the NIH. Further information can be provided by Dr. Bruce Rosengard of our ASTS, who is the Director of Cardiac Transplantation at the University of Pennsylvania in Philadelphia.

2.) In adapting some of the Spanish practices, we have begun, with the help of individuals previously with an organization called The Partnership For Organ Donation, to initiate *demonstration projects* in certain OPOs to amplify incentives in the hospitals in their areas to identify and maintain potential organ donors, an essential component of this model.

Reinforcement by HRSA and funding for both of these projects would aid them greatly. (We are proceeding independently with departmental knowledge and acquiescence, but not thus far with their financial help.) In any event, we expect these to demonstrate a positive impact within the next two years.

It was a privilege to appear before your Subcommittee. The bottom line of my message to you on behalf of the ASTS is that (1) we urge the Congress of the United States to reenact the National Organ Transplant Act (NOTA) to send a clear message as to its implementation by the Department of Health and Human Services. The message is that the decisions of organ allocation to save lives by transplantation must in the final analysis be under the responsibility and aegis of surgeons and physicians empowered to do so by law. (2) There must be sanctions applied by HCFA when rules promulgated by these surgeons, physicians, and their lay peers, i.e., the OPTN contractees, are not adhered to, to ensure optimum usage of these organs according to the highest medical and ethical precepts. This is the manner in which implementation of NOTA by the Executive Branch should occur. (3) Operational and educational initiatives to increase organ donations could well be incorporated into the law by a collaborative participation of our medical and paramedical experts with the help and direction of the Congressional leadership.

We indeed would welcome the opportunity to work closely with you in achieving these goals.

Sincerely yours,

JOSHUA MILLER, M.D., *President,*
American Society of Transplant Surgeons,
University of Miami School of Medicine

Enc.

MEDICAL COLLEGE OF VIRGINIA
April 27, 1999

The Honorable MICHAEL BILIRAKIS
Committee on Commerce
U.S. House of Representatives
2125 Rayburn House Office Building
Washington, D.C. 20515

DEAR MR. BILIRAKIS, per your request, I am answering the questions listed below.

Question 1. At the hearing, witnesses testified about numerous state programs to increase organ supplies. If Congress were to move to a national waiting list system, how would that impact existing state policies designed to increase organ supplies?

Response. A national waiting list would seriously undermine existing state policies designed to increase organ supplies. Organ donation appears to be a relatively regionally driven phenomenon. Areas where there is an active transplant center have historically had the highest organ donation rates. The idea that organs recovered in one area would be shipped across the country, I believe, would negatively impact that particular area's motivation to donate organs for transplantation. The most populated and urbanized states also have the largest numbers of patients needing liver transplantation. A nationalized waiting list would divert organs to the most seriously ill patients. Statistically, the majority of the organs that become available will, then, go to the centers with the largest numbers of patients. This would have several implications for centers in less heavily populated regions. Very few organs will become available for these centers and many would be forced to stop offering this service to their patients. Liver transplant recipients need not only intensive preoperative and immediate post operative care but also require skilled, continued follow up care. It is not cost effective to provide these specialized services for only a small number of patients. Patients would be forced away from their homes and families in order to receive life saving medical care. A nationalized waiting list would also shift the responsibility of instituting measures to increase the supply of organs away from the individual states and regions. The needs of the individual regions may be very different and nationalized policies may not serve them well.

Question 2. Pennsylvania has instituted a program that pays families of organ donors \$300.00 in state contributions for the donor's funeral expenses, starting this July. What is your opinion on this type of program?

Response. I agree. \$300.00 is not likely to spark too much more organ donation but it is a step in the right direction. We are not suggesting that cadaveric organ donors get paid per se, but there needs to be some incentive. The process of organ donation can interrupt the mourning process and delay funeral proceedings. While \$300.00 does not begin to pay the entire bill, it can make up for the slight inconvenience imposed by organ donation. Limited life insurance policies is another good suggestion. We at the Medical College of Virginia are the leading center on living donor adult to adult liver transplantation. Even though the donor operation is included in the cost of the recipient operation, nevertheless, donors have to come back to the hospital for medical check ups, lab work as a normal post operative period after a very delicate surgery. They need to stay out of work for at least three weeks to one month. We can see in this field that reimbursement for the lost time at work and in other expenses associated with living donor organ donation is also a reasonable incentive.

Question 3. The proposed HHS regulations to reallocate organs state that "the OPTN is required to develop equitable allocation policies that provide organs to those with the greatest medical urgency, in accordance with sound medical judgment." When President Clinton signed H.R. 3579, the Supplemental Appropriations and Rescissions Act, on May 1, 1998, which extended the public comment period and implementation deadline for the HHS OPTN regulations, he issued a written statement in opposition to extending the comment period on the rule. In stating his reasons for opposing the extension, President Clinton stated that "The final rule would ensure that organs are allocated to the sickest candidates first." What would be the supply side effects of a policy where organs were to be allocated to "the sickest candidates first"?

Response. This has been discussed in detail by PAT Coalition. Allocation to the "sickest first" on a national level will increase wait list mortalities, waste organs, increase retransplantation rates, disadvantage medically and economically disenfranchised segments of the population by limiting access to transplantation for indigent patients as smaller centers are forced to close their doors. The organs would be diverted to the most critically ill patients first, regardless of their location. While this may sound like a fair and reasonable way to allocate organs, a policy

such as this may actually result in lost lives. The immediate and long term survival of liver transplant recipients is directly dependent on their preoperative condition, with significant decompensation adversely affecting survival. Blindly applied legislation may mean that a significant number of organs are given to people with little chance of survival. Organs may not become available for others until they too are critically ill with little chance of survival.

Question 4. How do we increase the consent rates for families to donate organs? What recommendations would you offer to increase the number of individuals willing to donate their organs?

Response. Making drivers license decision a legally binding document (which it actually is in the state of Virginia, by the way) and limiting liability and exposure of OPO's with respect to families of individuals who have designated themselves donors on their license. Public education and education of medical community involved in identifying and deciding brain dead patients. "Required request" has already led to some increase. Further study of states/countries where "presumed consent" is operational is warranted.

Question 5. In your estimation, how would the Department of Health and Human Services regulation published April 2, 1998, affect your patients and your ability to provide the highest quality of medical care for them? What impact will this rule have on local access to transplant services nationwide?

Response. The portion of the April 2 HHS rule which would create a national wait list will severely limit access to transplantation for the indigent population by forcing small and moderately sized centers to close their doors. This concept is designed to support only a select few very large transplant centers, which would regionalize access to transplantation to only a few places in the entire country. It is obvious that moderately sized centers, such as our own, not only can provide high quality transplant patient services, but also provide the innovative driving force required to develop something like a "living donor adult-to-adult right lobe" liver transplant program, etc.

Question 6. Could you please explain to the Committee why some areas of the country have much higher rates of organ donation than others?

Response. In general, areas involved with a regional or local transplant center have the highest donation rates. Other factors include the socioeconomic and religious fabric of the regional culture, organization and effectiveness of OPO's, etc.

Question 7. As you know, the Department of Health and Human Services regulations have created quite an intense debate about the allocation of organs for transplantation. Some suggest, however, that the debate would be more constructive if it revolved around organ donation instead. What is your opinion?

Response. Very definitely organ donation is the problem, with allocation a distant secondary problem. Primary effort should be directed to increasing the number of organs available for transplantation. The present allocation scheme, although not perfect, should not be completely discarded, since it is working pretty well. Analysis of waiting time differences between regions in the country will need to await data generated AFTER uniform listing and medical urgency criteria have been in effect for some time, since to do so now is to compare apples to oranges.

Question 8. As the number of transplant programs across the country has grown, has the number of transplant procedures grown also? Can you elaborate on the estimated number of procedures which will be performed with the next five years?

Response. The number of procedures will continue to increase, but slowly, until or unless there is a major increase in supply of available transplantable organs either by increase in cadaveric donors, living donors, or xenotransplantation comes of age. Cadaveric donors are slowly increasing, and this slight increase is due to the willingness of transplant physicians and patients to consider organs from donors that in the past would have been not used due to the age of the donor or the events that surrounded the donors death. This is the so called "marginal" donor and it is through the use of the marginal donor that this increase has come about. The living donor is an excellent source of organs and since for every liver that is obtained from a living donor a patient on the waiting list that does not happen to be fortunate enough of having a living donor will automatically move up one step in the waiting list. Techniques like splitting livers can potentially double the number of organs available. Although it is important to know that splitting the liver will still only benefit one adult for every single liver that is procured. Therefore, with this technique, the shortage of organs for adults which is the main problem in America, can not be solved.

Question 9. In your opinion, does an active local transplant program stimulate organ donation?

Response. Very definitely so!!!

Question 10. What would you define as an appropriate role for the federal government in the formulation of transplant policy?

Response. Federal government should act as an oversight group for policies generated by National Transplant Community, as it has since NOTA was first enacted in 1984, and UNOS has administered the OPTN contract.

Question 11. Dr. Marcos, you were recently quoted in an interesting article entitled "Increasing Split Livers Will Decrease Organ Shortage," published in the American Medical News, on the importance of developing living donor transplants. You state in this article that 45% of the transplants you do are living donor transplants. What do you think the upper bound limit of living donor transplants is?

Response. 45% living donor livers in our program over the past year is a function of decline in cadaveric donors! It is hard to say what the upper limit is, but it will never fulfill the need for people on the wait list. Hepatitis C is epidemic, for example, and thus we might expect a large increase in end stage liver disease requiring liver transplant in the near future. As more organs become available through a living donor, patients that were not considered for transplantation in the past due to the shortage of organs, this being the case of patients with cancer of the liver, can be considered for living donor liver transplantation under very rigorous protocols.

Question 12. Given the severe shortage of livers available for transplantation, how prevalent do you foresee split liver transplants becoming within the next few years? How will the more frequent use of split liver transplants affect the length of the waiting list?

Response. Split livers only benefits one adult per liver. The other beneficiary will be a pediatric recipient. The pediatric shortage of organs has decreased significantly with the excellent use of the living donor adult to child liver transplant which has been happening all over the world. They per se are not the group of the population that is in desperate need of organs. Not only does splitting the liver offers one liver per adult, if any problems may arise from the use of the liver it will mean that it could potentially take at least two livers to benefit a single adult. Which would be working against the adults on the waiting list.

Question 13. I understand that the UNOS committee with responsibility for this area is recommending a rule that would increase the supply of livers by dividing them and encouraging greater sharing. When do you anticipate this new rule will go into effect?

Response. Ask UNOS. It seems to be too soon. I don't think it will be particularly effective. Splits have many more complications. Splitting livers can potentially increase the shortage for adult organs benefitting only pediatric recipients.

I hope I have successfully answered your questions. If you have any questions or concerns, please do not hesitate to contact me.

Sincerely Yours,

AMADEO MARCOS, *Assistant Professor of Surgery*
Director of the Living Donor Liver Program
Division of Transplantation

AMERICAN SOCIETY OF TRANSPLANTATION
April 30, 1999

The Honorable MICHAEL BILIRAKIS
Chairman, Subcommittee on Health and Environment
U.S. House of Representatives
Committee on Commerce
Room 2125, Rayburn House Office Building
Washington, D.C. 20515-6115

DEAR MR. BILIRAKIS: Thank you for allowing me to testify on behalf of the American Society of Transplantation (AST) before the Subcommittee on Health and Environment for the April 15, 1999 hearing entitled, "Putting Patients First: Increasing Organ Supply for Transplantation." The AST is strongly supportive of your leadership in advancing solutions to enhance organ donation, the most critical issue facing patients in need of organ transplantation.

At your request, I am here responding to the 14 questions you sent subsequent to the hearing.

Question 1. At the hearing, witnesses testified about numerous state programs to increase organ supplies. If Congress were to move to a national waiting list system, how would that impact existing state policies designed to increase organ supplies?

Response. It is not evident that a national waiting list system would have any impact at all on existing state policies designed to increase organ supplies. Indeed, it is important that we do not get caught in the trap of confusing donation efforts

with allocation. Any program that supports donation is valuable, but it should not be directly tied to allocation.

The congressionally mandated Organ Procurement and Transplant Network (OPTN) operates as a national waiting list system, coordinating the placement of organs throughout the country according to national, regional and local algorithms. This should not be confused with a single national waiting list, an artificially constructed proposed national sharing arrangement for a single pool of organ recipients, which is in fact, not endorsed by the OPTN contractor, UNOS, the Secretary of Health, or the AST.

While many groups have worked hard to increase donation, including the national and local governments, UNOS, professional societies, patient groups, etc, there should be agreement that the 62 organ procurement organizations (OPOs) form the local nucleus of organ donation and recovery. We hope that State efforts work in concert with the local OPOs that have responsibility for organ donation and recovery in their states to ensure maximum yield. So too, must national and state policies work hand in hand to promote the optimal donation, recovery and transplantation of these precious organs. Certainly, a national policy of organ distribution should be fashioned, to the extent possible, in a manner which will enhance organ recovery in the states and not discourage it in any way.

Question 2. Pennsylvania has instituted a program that pays families of organ donors \$300 in state contributions for the donor's funeral expenses, starting this July. What is your opinion on this type of program?

Response. We support carrying out creative pilot studies to explore the possibility that quite modest financial supports may enhance organ donation, such as the one in Pennsylvania. In my testimony, I also mentioned the support currently being provided to organ donation by the state of Georgia. In the Georgia program, driver's license renewal fees are discounted by \$2.00 for those who designate their wishes to be organ and tissue donors. These experiments should be carried out under carefully controlled conditions, and their results should be thoroughly examined. If such programs are successful, opportunities for broader application should be sought. However, with any and all such efforts, we must respect and preserve the basic underlying altruism and public trust, which is the foundation of organ donation.

Question 3. The proposed HHS regulations to reallocate organs state that "the OPTN is required to develop equitable allocation policies that provide organs to those with the greatest medical urgency, in accordance with sound medical judgement." When President Clinton signed H.R.3579, the Supplemental Appropriations and Rescissions Act, on May 1, 1998, which extended the public comment period and implementation deadline for the HHS OPTN regulations, he issued a written statement in opposition to extending the comment period on the rule. In stating his reasons for opposing the extension, President Clinton stated that, "The final rule would ensure that organs are allocated to the sickest candidates first." What would be the supply-side effects of a policy where organs were to be allocated to "the sickest candidates first"?

Response. We must first understand that medical urgency is most suitably applied to the instance of life-saving organ transplants such as the heart or liver and only more selectively to life-enhancing organ transplants like the kidney or pancreas. In the case of hearts and livers, the present system of allocation is strongly weighted toward the sickest patients with the greatest medical urgency, and in fact because of broader regional sharing for such organs, the waiting times for these "Status 1" patients are quite similar throughout the nation. Importantly, we must also continue to balance practical concerns for utility, especially for the majority of potential organ recipients so that overall results are optimized. It can be argued that reserving the allocation of organs to only the sickest candidates may decrease the overall good that can come from these organs. This is because the sickest candidates, even if transplanted, are more likely to die than are transplant recipients who are less ill. Put another way, policies that increase the number of organs that are allocated to the sickest will likely reduce the total number of individuals who live with functioning transplants. Of course, all of this results from a donor shortage that forces us to explicitly ration organs one way or the another.

Question 4. How do we increase the consent rates for families to donate organs? What recommendation would you offer to increase the number of individuals willing to donate their organs?

Response. Family refusal is a major impediment to organ donation despite the fact that national public opinion polls have demonstrated that more than 75% of individuals profess to be supportive. Clearly we must find new ways to better translate this public awareness into action with higher consent rates. We must work diligently to solve this problem through research efforts, epidemiological studies, and public awareness campaigns. We must better define those factors characterizing the

most successful OPOs and support the appropriate extension of effective strategies to other areas of the country. We must also be willing to support and study innovative local/state initiatives to increase organ donation. Indeed, it is encouraging that the Division of Transplantation, located in the Health Resources and Services Administration has recently issued a request for proposals (RFP) to increase organ and tissue donation. By identifying and understanding the fundamental characteristics of successful strategies, we will become more successful and more cost-effective in our future efforts.

Question 5. In your estimation, how would the Department of Health and Human Services regulations published April 2, 1998, affect your patients and your ability to provide the highest quality of medical care for them? What impact will this rule have on local access to transplant services nationwide?

Response. The impact of these regulations on the quality of medical care would depend upon the formulation of the policies of allocation by the OPTN. Those allocation policies will determine who gets transplanted but should not affect the care provided by physicians to transplant recipients. There is no evidence that broad sharing will diminish local access. In fact, there are data that demonstrate that new local programs flourish in areas that have broad sharing.

Question 6. Could you please explain to the Committee why some areas of the country have much higher rates of organ donation than others?

Response. According to the current measure of donation rates (donors per million base populations), there is significant variation in the performance of OPOs. Many factors play a role in the variation in organ donation rates, such as the characteristics of the local population and the commitment of resources provided by the local OPOs. However, it is also broadly recognized that this measure (donors per million base populations) is flawed and does not provide accurate data. Newer measures, such as donors/1000 deaths or conversion rates of acceptable donors may be better measures. An ongoing Association of Organ Procurement Organization (AOPO) study has already shown that OPOs that appear to be functioning poorly by one measure may be outstanding by another. Until there is clearer agreement on appropriate outcome measures, we can't fully answer this question. Nevertheless, it is probable that some OPOs are more successful in converting potential donors into actual donors, and we should attempt to identify explanations. Ultimately, if we can identify reasons for differences in retrieval rates, then we may be able to exploit this knowledge to improve the performance of all OPOs.

Question 7. As you know, the Department of Health and Human Services regulations have created quite an intense debate about the allocation of organs for transplantation. Some suggest, however, that the debate would be more constructive if it revolved around organ donation instead. What is your opinion?

Response. These are two separate issues, each requiring careful consideration. If we had a sufficient supply of transplantable organs, the allocation questions could be more easily addressed. However, with our current serious shortage, the allocation debate tends to drown out discussions about donation, as UNOS and most OPOs have discovered. This is unfortunate as indeed, both are critically important, and both must be addressed separately.

Question 8. As the number of transplant programs across the country has grown, has the number of transplant procedures grown also? Can you elaborate on the estimated number of procedures which will be performed within the next five years?

Response. It is impossible to say for certain whether increases in the number of transplant programs has increased the number of procedures, or has only shifted procedures to other centers. However, given the reality of the present donor shortage, it is unlikely that further expanding the number of transplant centers will significantly increase the number of transplants performed. The number of donors inevitably limits the number of transplants.

The number of transplants has increased modestly because of innovative techniques to increase the number of grafts per donor (e.g., split livers, transplanting two halves of a liver into two patients), decreasing organ "wastage" through the increased use of "extended donors," and increased numbers of living donors for kidney and liver transplantation. At our current rate of donation, approximately one hundred thousand organ transplants are likely to be performed over the next five years. Unfortunately, this number will provide for less than 25% of those on the waiting list.

Question 9. In your opinion, does an active local transplant program stimulate organ donation?

Response. In the early years of development of transplantation science and clinical practice, transplant programs and organ procurement programs were tightly linked. The activity of one was inexorably tied to the other. In the current era, transplant centers and OPOs are quite often separate and independent. Some have

speculated that even in the present day, the activity of a local transplant program enhances local efforts to procure transplantable organs, though there are no data that substantiate this hypothesis. It is possible, for example, that interest stimulated by press reports of local transplant efforts could stimulate local organ donation. The argument can be made that individuals who read about others in their community receiving transplants may be more likely to sign a donor card, etc. However, we are not aware of any studies showing that there has been a greater-than-expected increase in local donation when a new transplant program opens. The recently implemented federal rule of required referral as a condition of participation in Medicare will likely diminish this influence if it does exist in any locales.

Local transplant programs should be encouraged, first and foremost, when their presence provides improved access to care. If they also increase donation, that is an added bonus. Current experience demonstrates that local programs do thrive in areas with wide sharing.

Question 10. What would you define as an appropriate role for the federal government in the formulation of transplant policy?

Response. The transplant community should create through consensus and scientific research, the policies, which provide for organ transplantation in this nation. The federal government should provide appropriate oversight and authority to such policies so that they may be effectively implemented.

Question 11. You stated in your testimony that a lack of leave time has served as a significant barrier and disincentive for individuals willing to share the gift-of-life. What are the recovery times for kidney and liver donors?

Response. Living donation is currently under utilized. It is important to identify and alleviate any and all disincentives to this important altruistic behavior. Part of that process is the recognition that kidney donors typically require 4-6 weeks of recovery and time away from work. For liver donors, this is typically in the range of 6-8 weeks.

Question 12. From 1988 to 1997, the annual number of kidneys donated by living persons rose 104 percent, from 1,812 to 3,705. What brought about this increase?

Response. It is likely that the recent increase in living donors, including biologically unrelated donors, has been due to a combination of factors. Living donors have been strongly motivated to donate because of the increasing waiting times for cadaveric donors. In addition, altruism has increased with the demonstrated success of the procedure. It is also now recognized that the success of living donor transplants, including living unrelated kidneys, is better than that of cadaver organs.

Question 13. As transplant centers use new techniques to cut recovery times, will that have the effect of increasing donation? Can you comment on the new surgical procedure at Johns Hopkins that is cutting the recovery time of kidney donors?

Response. While it appears that only a small percentage of potential living kidney donors are dissuaded to donate simply because of the concern for morbidity with the standard surgical techniques, many transplant centers around the nation are now or soon will be utilizing the laparoscopic approach to donor nephrectomy as an elective alternative. The early results of this experience suggest that although hospital lengths of stay and donor recovery times are slightly shorter, other complications can arise. More research is necessary before concluding whether such techniques will appreciably enhance living donation.

Question 14. Your written testimony requested that "increased funding be provided to the Division of Transplantation, located in the Health Resources and Services Administration ("HRSA") with additional funds for FY2000." My understanding is that Congress gave \$5.9 million above the President's request for the "Extramural Support Program to Increase Organ and Tissue Donation" for Fiscal Year 1999, and the Administration's request for proposals was just published on April 5, 1999. Can you explain why the Health Resources and Services Administration only recently requested this additional funding?

Response. It is not unusual that several months are required to develop an adequate RFP and review process when a new competitive contract is announced. We are confident that there will be many applicants for these contracts and that the money will be awarded in FY 99.

Thank you again for the opportunity to provide testimony. The AST stands ready to assist you and your committee in any way that we can to enhance the opportunities for patients in need of organ transplantation.

Sincerely,

JOHN F. NEYLAN M.D.
President, American Society of Transplantation

MICHAEL BILIRAKIS, *Chairman*
Subcommittee on Health and Environment
U.S. House of Representatives
Committee on Commerce
Room 2125
Rayburn House Office Building
Washington, DC 20515-6115

DEAR REPRESENTATIVE BILIRAKIS: I am writing in response to your April 21, 1999 request in follow up to my April 15 appearance before the Subcommittee on Health and Environment on Putting Patients First: Increasing Organ Supply for Transplantation. Just as I testified on April 18, I am responding as President and CEO of Gift of Life Donor Program (formerly Delaware Valley Transplant Program ["DVTP"]) and President of the Coalition on Donation.

The number of each item corresponds with the number in your April 21 letter:
Question 1. At the hearing, witnesses testified about numerous state programs to increase organ supplies. If Congress were to move to a national waiting list system, how would this impact existing state policies designed to increase organ supplies?

Response. There are no current state policies/ laws in Pennsylvania, New Jersey or Delaware that address organ allocation. We follow national policies and guidelines for the allocation of all organs. I do not believe that allocation should be restricted in any way by state law; this would go against the intent of the existing statutory model which provides for a national transplant system.

The existing state organ donor laws address programs to increase organ and tissue donations. As you are aware, the "Routine Referral" law passed in Pennsylvania in 1994 has resulted in significant increases in organ donations. We anticipate that additional steps forward in reducing the organ shortage will occur with the implementation of the "Routine Referral" standard for Medicare and Medicaid participating hospitals.

By and large, we believe that the greatest impact of the current debate and attempts to mandate change in the allocation of a scarce national resource has been to harm public trust in the organ donation and transplant system. The current system has been characterized as being broken and unfair to most patients. That simply is not true.

While historically there have been discrepancies in waiting times by region, those discrepancies are in large part based on a system of organ allocation that no longer exists. Major changes to the liver and heart allocation policies have been instituted during the past two years to ensure that the sickest patients receive priority to the extent medically feasible. I believe that today's data would reveal very different results than data from 1996 upon which the current organ allocation debate is framed.

Question 2. Pennsylvania has instituted a program that pays families of organ donors \$300 in state contributions for the donor's funeral expenses, starting this July. What is your opinion on this type of program?

Response. In 1994, the Pennsylvania legislature enacted a comprehensive law promoting organ donation in the Commonwealth. This pioneer legislation included the Routine Referral standard that has become a national model. The legislature recognized that in order to effectively combat the organ shortage, an effective public education and awareness campaign had to be instituted. This included the establishment of an Organ Donation Awareness Trust Fund which has among its stated purposes the financial support of organ donation awareness programs. Included in the legislation was the mandate for development of a pilot program such as the Voluntary Death Benefit Program which will allow limited reimbursement (directly to the provider, such as the funeral home) of certain donor family expenses. Under the guidance of a Organ Donation Advisory Committee, and various state agencies, along with involved legislators and citizens, the Commonwealth is seeking to implement the pilot Voluntary Death Benefit Program provided for under the legislation. The Voluntary Death Benefit Program has not yet been instituted. Final recommendations for this program will be made on June 9 to the Secretary of the Pennsylvania Department of Health and then to Pennsylvania Governor Tom Ridge. This program is but one component of a comprehensive approach to increasing organ donations in the state.

In the context of Pennsylvania's overall organ donor law, we believe that the pilot Benefit program should be tried and that it may impact donation rates by providing another contact with families so that they can receive information regarding organ donation. We are doubtful that the "benefit" (which is anticipated to be no more than \$300 and which will be paid directly to the funeral to reimburse for costs) will

have an immediate or noticeable impact on consent rates. However, over time, the discussion regarding the availability of the benefit may lead more people to be familiar with the concept of organ donation.

Question 3. The proposed HHS regulations to reallocate organs state that "the OPTN is required to develop equitable allocation policies that provide organs to those with the greatest medical urgency, in accordance with sound medical judgment." When President Clinton signed H.R. 3579, the Supplemental Appropriations and Rescissions Act, on May 1, 1998 which extended the public comment period and implementation deadline for the HHS OPTN regulations, he issued a written statement in opposition to extending the comment period on the rule. In stating his reasons for opposing the extension, President Clinton stated that "The final rule would ensure that organs are allocated to the sickest candidates first. What would be the supply-side effects of a policy where organs were to be allocated to the 'sickest candidates first?'"

Response. We believe that the current system of policy development is sound. It is based on consensus building and medical judgement. Major changes to the liver and heart allocation policies have been instituted during the past two years by the Organ Procurement and Transplantation Network ("OPTN") contractor, the United Network for Organ Sharing ("UNOS"). This includes standardized listing criteria for patients and changes to the status designations for liver and heart patients. We believe that the current system, while not perfect, is designed to ensure that the sickest patient is offered the organ first. We know in our region that the vast majority of patients receiving heart and liver transplants are transplanted at the highest level of acuity and are the sickest patients in our region.

We believe that further changes to mandate a single national list for allocation, may lead to organs being wasted and potential donors lost given the attendant medical and social issues.

Question 4. How do we increase the consent rates for families to donate organs? What recommendations would you offer to increase the number of individuals willing to donate their organs?

Response. There is no one answer to the issue of increasing consent rates. Expanded public education programs combined with best-demonstrated practices in hospitals can lead to increased consent rates.

National public education campaigns such as those conducted by the national Coalition on Donation can, over time, impact public opinion and encourage people to take action. The major limitation to public services campaigns and initiatives is funding. Although the Coalition campaign is the major public education initiative in the United States, it receives no grant money or funding from the Federal Government.

Other initiatives that should be explored include the creation of statewide registries or a national registry of organ donors.

Pennsylvania's Drivers License Donor registry is now the second largest in the nation (Illinois has the largest). The Pennsylvania Drivers License Donor registry provides an important opportunity to educate citizens and to record their decisions about organ donation. In addition to Pennsylvania and Illinois, Florida, Delaware, Georgia, Louisiana, Maryland and Missouri have similar registries. Additionally, as stated in my April 15 testimony:

The Ad Council, in conjunction with its tremendous talent and more than 50 years of communication expertise, has created four campaigns that have been distributed to more than 30,000 media outlets in the past six years.

The James Redford Institute for Transplant Awareness developed a film to educate teens about donation and transplantation and has partnered with the Coalition to distribute the film nationwide for the 1999-2000 school year.

Through the Coalition, Congress and the transplant community successfully partnered to distribute more than 60 million donor cards in 1997 as provided by the National Donor Card Insert Act.

The U.S. Postal Service working with the Coalition to promote the issuance of and distribution of an organ donor awareness stamp in 1998.

Significant also is the anticipated announcement by a major motion picture studio that it will create a new public service campaign for UNOS and the Coalition. This will include the development of public education pieces on organ donation and transplantation by a number of nationally recognized ad agencies.

We believe that on-going focused public awareness initiatives are critical to addressing the organ shortage.

Question 5. In your estimation, how would the Department of Health and Human Services regulations published April 2, 1998, affect your patients and your ability to provide the highest quality of medical care for them? What impact will this rule have on local access to transplant services nationwide?

Response. Mandating a national allocation system for all organs is likely to spur growth at a few large centers in the country but may impact the viability of smaller programs. This may have the effect of reducing or inhibiting access to services by those recipients and their families who are not able to travel to large centers due to economic and other barriers. Additionally, mandating a national allocation system of organs will eliminate the concept of local neighbor helping neighbor. Complete elimination of the concept of neighbor helping neighbor may adversely impact donation. Finally, a national allocation system disregards differences in medical judgment and opinion. It also disregards the practices of transplant surgeon who perform the organ recovery and view the organ in the donor patient and evaluate biopsy results (for livers) in order to evaluate suitability for transplant generally, as well as suitability for a specific recipient.

Question 6. Could you please explain to the Committee why some areas of the country have much higher rates of organ donation than others?

Response. This is a complex question. Donation rates are a combination of level of public support, hospital participation, demographics of the local population, performance of organ procurement organizations and willingness of transplant surgeons to use expanded donors and non-heart beating cadaver donors.

Our organization commits significant resources to grass roots public education. We also have extensive hospital development and education programs. We have very strong relationships with key physicians and health care professionals in our hospitals and are largely viewed as an extension of the hospital's care team. These partnering relationships enable our staff, who are specially trained in the process of interacting with grieving families regarding donation, to play a leading role in the consent discussion with families. Many OPOs, quite simply, do not have the same collaborative relationships with their regional hospitals and health care professionals. These relationships are critical to assuring that families are advised of the donor option in a sensitive and caring manner and are provided with all of the information needed in order to make a decision regarding donation.

Question 7. As you know, the Department of Health and Human Services regulations have created quite an intense debate about the allocation of organs for transplantation. Some suggest, however, that the debate would be more constructive if it revolved around organ donation instead. What is your opinion?

Response. We agree with this statement. As we have stated in numerous public forums it is only by implementing measures that increase the number of organs donated that our nation can address the critical organ shortage that exists in this country. Rather than completely overhauling a system that has had much success, attention must be focused on donation. The Routine Referral laws which have been enacted must be fully implemented along with comprehensive donor education programs. We urge Congress and HHS to support donor awareness efforts through public education programs. Financial support must be committed to strengthening the nation's understanding of the options families face when their loved ones die.

We also believe that the public debate over allocation during the past few years has adversely impacted the public's view of the donation process. Any debate regarding allocation must be conducted in a thoughtful and responsible manner so that those who have donated understand the positive impact of their gifts.

Question 8. As the number of transplant programs across the country has grown, has the number of transplant procedures grown also? Can you elaborate on the estimated number of procedures which will be performed within the next five years?

Response. We believe that the data demonstrates that more people who are medically suitable candidates for transplantation will undergo transplantation if the services are available in local communities. Citizens and community doctors have become well educated about the success of transplantation and the availability of services in local communities.

Question 9. In your opinion, does an active local transplant program stimulate organ donation?

Response. We believe that active local transplant programs heighten the public's awareness and understanding of the issues surrounding donation and transplantation. By virtue of the fact that more members of the local community are involved in donation and transplantation issues, the organ donor shortage is a prominent and well publicized issue in the media in our communities.

Question 10. What would you define as an appropriate role for the federal government in the formulation of transplant policy?

Response. The Federal Government's primary objective should be to maximize and encourage organ donation through appropriate public policy initiatives and with funding programs for education.

Question 11. How do you expect the supply shortages to be impacted by the implementation of routine notification policies? In Pennsylvania, we saw substantial in-

crease in organ donation after the program took effect. Are we likely to see similar increases nationally as a result of the new Conditions of Participation for Medicare and Medicaid?

Response. We believe our experiences in Pennsylvania can and will be replicated in other parts of the country. As I testified on April 15, in just four years after enactment of the law, the number of donors that our program coordinated in its Pennsylvania service area increased by 43%. Similarly, the number of actual organ transplants that we coordinated in 1998 was 50% greater than the number we coordinated in 1994. This growth occurred at a time when organ donations nationally increased an average of less than 2-3% a year.

Preliminary data reveals that national organ donation rates for calendar year 1998 are approximately 5.5% higher than the donation rates for calendar year 1997. The most significant increases appear to have occurred the last four months of 1998; the four months following the effective date of the federal Routine Referral rules. I anticipate that just as our donation rates have continued to rise, the national rates will continue to rise with Congress' full support of this federal Routine Referral standard and the continued cooperation of the medical community.

Question 12. Is the National Donor Card Insert Act succeeding in its goal of increasing organ supplies?

Response. The National Donor Card Insert Act was a one-time program to distribute cards with income tax refunds. We believe that any method of distributing donor cards and information to millions of Americans is worthwhile. This program is worth repeating. Given the appropriate time and financial resources, the Coalition could develop enhanced programs for evaluating programs like this one.

Thank you for the opportunity to provide additional information. Please do not hesitate to contact me at 215-557-8090 if you have any questions.

Sincerely,

HOWARD M. NATHAN, *President and Chief Executive Officer*
and *President, Coalition on Donation*

PROJECT DONOR

Gene Epstein
 Alan Boessmann, DVM
 1238 Wrightstown Road
 Newtown, Penna 18940
 215 968 2200

After two years of extensive research we wish to announce that the **Project Donor** report is complete. **Project Donor is an ethical, simple, supremely cost-effective means to solve the organ donation shortage by providing everyone a clear incentive to donate organs for transplantation through the government issuance of a \$10,000.00 free life insurance policy.** We currently have dozens of prominent people in the transplant community supporting it. Implementation of Project Donor will save the lives of those who are currently on organ waiting lists.

"Organ Donor" on a driver's license by itself is meaningless since no doctor will attempt a transplant fearing lawsuits. Project Donor is an actual insurance contract with explicit directives for organ recovery.

Note: For those who correlate the payment of money for organs as being unethical we agree. ***This is not the case!*** A life insurance policy assumes correctly that one day we all will die. The insurance companies are not paying for us to die nor encouraging it. On the contrary they make their money when we live longer. **Since there are numerous caveats in the insurance contract the actual value of the annual premiums is approximately \$2.00. yet under ideal situations the designated beneficiary will receive the sum of \$10,000.**

**Thank you
 Project Developers**

**Gene Epstein
 Alan W. Boessmann, D.V.M.**

*The enclosed report was prepared and written by
 Alan Boessmann, (liver transplant recipient)*

SOLVING THE ORGAN DONOR SHORTAGE

Today we possess the ability to extend lives through organ transplantation however only a chosen few will be the recipients due solely to the shortage of organ donations. After twenty years of publicizing the need, we should have an abundance of donors but we do not. The transplant community has not been successful enough in marketing the need.. In reality we are losing thousands of lives each year and spending hundreds of million of dollars trying to extend the lives of those desperately waiting for an organ transplant. *Too many will die waiting. Will it be your brother or mother, daughter or you?*

When a person dies the family is notified as soon as possible. A grieving family is not comforted when a doctor or transplant representative asks "can we take organs from your loved one's body?" Even though a donor card may be found in the possession of the deceased the doctors will and do request a positive YES from the next of kin prior to removing necessary organs. Families go through gut wrenching discussions never knowing if they are doing the 'right thing'. Doctors and hospitals are afraid of lawsuits without definitive instructions from the next of kin. If too much time is lost tracing the family or the family takes too long to make a positive decision then the organs will be useless and all is lost once more. Life through transplant requires a rapid and positive response.

With today's technology we sustain life while one awaits an organ. Whether hospitalized or passively waiting the costs to the healthcare system is enormous. It is not unusual to see hospital bills exceeding \$10,000 weekly while a needy dying patient waits.

The preceding has led us to formulate a plan that would eliminate the shortage while being cost effective, ethical, comforting, and even generating income tax revenues from those able to return to the workforce.

'Project Donor' proposes an incentive to sign a definitive authorization. A no cost LIFE INSURANCE POLICY contract in the amount of \$10,000.00 which will be issued by the U.S. government payable to the directed beneficiary upon the transplant of an organ (s) from the deceased.

BENEFITS;

- Secure an abundance of potential donors thus saving thousands of lives.
- Definitive and simplified instructions in the policy will eliminate the decisions by the grieving family.
- Doctors will be relieved that they will not have to convince relatives of the need.
- Hospitals will not have to worry about being sued.
- Organs will be readily available without the chance of deterioration.
- 45,000 patients will receive needed transplants.
- Hospital stays will be dramatically shortened saving far more than the cost of the benefits paid out.
- No need to have insurance medical exams since the 'caveat' clearly states that the organ(s) must have been transplanted.
- In many instances the recipients will be able to return to productive lives.
- And the families whose lives were devastated waiting for an organ will be able to realize a bright future.

WHY THE NEED FOR PROJECT DONOR ?

In 1986 my sixty-three year old brother Wesley , was in need of a heart transplant. He had been through eight heart attacks over the years and only a small per cent of his heart was functioning. After taking him to Temple University Hospital, Hanheman Hospital and Holy Redeemer Hospital we were told that Wesley had 24 hours to live. I Fed-Ex'd his records across the country to every heart transplant group and everyone refused to do a transplant because of his age . However Pittsburgh Presbyterian was willing providing I could put up a \$100,000 line of credit. They were uncertain if they would receive any payment from the government, remembering that this was in the early stages of organ transplantation and still considered experimental.

Upon providing this line of credit I medivac-ed him to Pittsburgh. The following day a heart was made available . But did someone die waiting?? I remember sitting in the family waiting room while my brother was in surgery. I watched others whose loved ones were on life support . They prayed for the door to open and a doctor to walk in and say 'We just got an organ'. But it didn't happen.

Did my brother get one that they were waiting for? I don't know. It has troubled me for years. Why aren't there enough organs to save everyone's life? I was certainly elated that Wesley could lead a somewhat normal life and that the doctors who gave him 24 hours to live were wrong by twelve years. But I felt compelled to do something to make up for my actions..

About two years ago , during a sleepless night, I conceived 'Project Donor'. I thought that if there were some kind of incentive for people to be donors it would increase the number of organs available each year and the nightmares of those dying while on a waiting list would go away.. What type of incentive would work ? I decided on an insurance policy with no premiums that would be offered free by the federal government as an incentive to everyone to sign an insurance contract to donate their organs . After all I assumed that if you could save a life what is the difference how much it costs? At that time I never 'crunched' the numbers because I naively believed that money would never stop the government from saving lives.

I thought that the amount of \$10,000 payable in the event of death to a designated beneficiary that had several caveats including the most obvious , that the organs must be transplantable , would encourage most young couples to sign on. They would know that there would be some money to take care of medical bills and funeral expenses in the event of their spouse's death and they would avoid leaving their spouse or other family members the stress of deciding what to do with their body.

As I got further into discussions with doctors I remembered the troubled look on the faces of family members and doctors alike when discussing removing organs for someone else. It is so traumatic to occur at that time. Why couldn't it be discussed ahead of time with a written directive that was definitive ?

Project Donor will solve the organ donor shortage , immediately and cost effectively while alleviating the trauma to family members and doctors alike.

PROJECT DONOR

Why have it ?

I have been asked that question countless times. The answer is that after nearly twenty years informing the public about the need for organ donation we still have a dramatic shortage with nearly four thousand people dying annually.

Why must there be a life insurance policy ?

When a person dies the loved ones are usually in a traumatic state. They have just been informed that he or she has died and they need consoling not decision making with visions of their loved one's body parts removed.

A written life insurance contract implicitly expresses the wishes of the deceased which will direct the organ program, doctors and hospital to recover useful organs. With such a program the removal of organs will alleviate the legal fears that doctors and hospitals have today. The family will actually be grateful that this gut wrenching decision was made for them by the donor.

Today in many states people believe that they are donors simply because their driver's license shows it. But what happens if they changed their mind a week later ? Most states have two to four years licenses. What provisions does Project Donor have if someone changes their mind after signing for the insurance policy ?

The insured only needs to send to the offices of Project Donor a registered letter or form stating they wish to be removed from the list. Upon receipt of such notice their name will be immediately removed.

Do you feel that offering to pay the sum of \$10,000 for organs is unethical besides being illegal?

Absolutely : however this is not the case. We are proposing that the government offer a no cost life insurance policy as an incentive with many caveats as described within our text. It is simply as an insurance policy the annual cost of such a policy premium (if it were to be available) would be under two dollars per year.



THE VICE PRESIDENT
WASHINGTON

June 30, 1998

Mr. Gene Epstein
1238 Wrightstown Road
Wrightstown, PA 18940

Dear Mr. Epstein:

Thank you for writing and for sending me a copy of your organ donation proposal. I appreciate your thinking of me and sharing your plan with me.

As you may know, I have been working throughout my career to improve our citizens' access to transplant services. Since coming to office, the President and I have continued to pursue policies that will increase awareness about organ donation throughout the nation. Working with public and private sector partners, we hope to increase organ donation by 20 percent within two years. In March of 1998, the Secretary of Health and Human Services announced a new regulation to improve the nation's organ transplantation system to help assure that patients with the greatest medical need will receive scarce organs based on medical judgment and common medical criteria, no matter where they live or in what transplant center they are awaiting treatment.

Again, thank you for sharing your ideas with me. Your proposal will be helpful as we work to improve the organ allocation system in the United States, and your suggestions will be given careful consideration. Please accept my best wishes.

Sincerely,

A handwritten signature in dark ink, appearing to read "Al Gore", written over a horizontal line.

Al Gore

AG/wem

THE WHITE HOUSE
WASHINGTON

December 11, 1998

Sir Eugene Epstein
1238 Wrightstown Road
Newtown, Pennsylvania 18940

Dear Gene:

Thank you for your letter and the information on Project Donor. I appreciate your thinking of me. I have forwarded the information to Bruce Reed, Assistant to the President for Domestic Policy.

As President Clinton continues to prepare this country for the next century, your input and support are important. I hope you continue to stay involved.

Again, thank you for writing.

Sincerely,



John Podesta
Chief of Staff

cc: The Honorable Bruce Reed

Project Donor

15310 Pinion Road • Reno, NV 89511 • (702) 852-7121

Highlights

Project Donor is the solution to the organ donation shortage. Ten people die every day waiting for an organ. An easy, simple, cost-effective incentive to obtain the requisite donations is a life insurance policy furnished by the United States Government, benefits to be payable upon the donation *and transplantation* of the deceased's organs.

The numbers pertaining to the supply of and demand for organs in the United States are such that the problem is statistically solvable. At the very least, we can provide organs to the eleven people who die every day waiting. Page 10 of the Project Donor Report details the figures as of the "snapshot" taken in April, 1998.

The Gallup survey of 1993 conducted for the Partnership for Organ Donation showed that Americans appreciate the value of organ transplantation and approve its use as a medical therapy. Nevertheless, there is a low rate of organ donation for reasons which are not convincing or deeply held. Recognizing and preparing for your own death, a requirement for making a decision to be a donor, is ripe territory for benign neglect. What is needed is an ethical, compelling benefit, used as an incentive, to overcome people's reluctance to act when confronted with this distasteful situation and convince them to give a gift by way of a directed decision to becoming an organ donor.

This benefit/incentive is Project Donor's United States Government Organ Transplant Life Insurance Policy. A no-cost organ transplant life insurance policy in the amount of \$10,000.00 is issued by the United States government or a Congressionally chartered non-profit organization, the benefit payable to a directed beneficiary, upon the transplant of any one or more major organs from a deceased individual. The donor card and/or life insurance contract are revocable by the donor. The names of the beneficiary(s) are strictly confidential, inaccessible to family members, medical personnel and others. The donor card and insurance contract are binding and enforceable in a court of law. No member of the donor's family has the right or power to void the agreement, pursuant to the Uniform Anatomical Gift Act (1987), Section 2.(h).

The quid pro quo use of a benign, common and popular financial instrument as a stimulus for public good is not only customary in our society, but is consistent with the financial payments made to doctors, hospitals, transplant organizations and health insurance companies. The United States Government Organ Transplant Life Insurance Policy's benefit payment is as ethical as any other life insurance benefit payment.

In addition to signing donor cards, the insurance policy and its enforceable contract will succeed in:

- eliminating painful decisions by the grieving family of a deceased because the deceased will have clearly indicated his or her desire to donate and the formal recording of legal documents will empower Section 2.(h) of the Uniform Anatomical Gift Act.
- eliminating painful donor requests by doctors and administrators of the deceased's family.
- eliminating hospital concerns over lawsuits by establishing a contractual basis for the expeditious acquisition of organs.
- establishing a national donor registry for use in carrying out donors' wishes.

The estimated cost of insurance benefits to the public (vis-a-vis the United States government) as of April, 1998, would be approximately \$158 million (amortized over time) to transplant those people currently waiting for organs other than kidneys and \$96 million annually for those added to the list each year.

The estimated savings in health care costs for these same transplant patients as a result of promptly transplanting them is over \$2 billion annually.

For kidney transplants which comprise the majority of transplant patients, the net discounted savings *per patient* is \$42,000 over a 10-year time frame, or better.

The above figures change as additions to the transplant list are made. Nevertheless, **Project Donor provides a huge projected net financial savings to society.**

The savings must be utilized to save lives through transplantation. There must be no windfall financial gain to anyone.

Legislation must be enacted to implement Project Donor, including possible amendments to the Uniform Anatomical Gift Act and the National Organ Transplant Act.

April 15, 1999

Project Donor

15310 Pinion Road • Reno, NV 89511 • (702) 852-7121

Questions and Answers

Q: Is Project Donor paying for organs?

A: No. This is not a buy/sell agreement. This is an insurance policy. It is an incentive for individual members of the public, *not* their families or any other third party, to become organ donors. The beneficiaries of the life insurance policy are not receiving valuable consideration for the donation of organs because they are not donating—the donor is. Consequently, the beneficiaries would not even be aware they are beneficiaries unless the policy holder told them.

This is a personal life insurance contract that simply specifies death and transplantation as the criteria necessary for the payment of benefits. Accidental Death and *Dismemberment* policies pay for the relinquishment of a body part. Project Donor's insurance policy and these policies are identical in that the owner of said body parts prefers that he or she keep them, but also chooses that they be indemnified for their surrender.

The donation is still a voluntary gift.

Q: Would this plan put us on a slippery slope to buying and selling organs?

A: No. Life insurance is a common financial instrument.

Q: Is the \$10,000 insurance benefit payment too much or too little?

A: No. \$10,000 dollars is a significant incentive while not being mercenary.

Q: Should there be a sliding scale of payments made for the donation of different organs?

A: No. This is a benevolent incentive, not trafficking in organs.

Q: Is Project Donor taking advantage of the poor in that the incentive is more compelling to them than the wealthy?

A: No, it is not manipulating poor people. The poor may indeed be more apt to respond to the incentive, but they are more likely to do many things in society for financial reasons that the wealthy would not, such as working three jobs. Remember though, the dramatic

advertising and promotion of the unique and creative concept of Project Donor will bring the altruistic nature of organ donation to all segments of society, and we may find "upper class" registrants equaling those of the lower economic strata. This is an individual, voluntary acceptance of a government program, with no coercion, just as acceptance of Medicare benefits is strictly voluntary.

Q: Would beneficiaries kill the insured in order to receive the benefit payment?

A: This is highly unlikely. The murderer would know they are killing someone for only \$10,000 *and* that the victim must be maintained on life support *and* that the victim would satisfy the medical requirements for donation *and* that an organ is indeed recovered and transplanted. The murderer must also know they are the beneficiary and think they will get away with the crime. Murders for insurance proceeds are certainly not unheard of in America, but there is certainly far less risk with the Project Donor policy. If one wanted to preclude this policy on this basis, one would have to ban all insurance policies.

Q: Would donors commit suicide to provide the benefit payment to their beneficiaries?

A: A perpetrator of suicide would be subject to essentially the same conditions and restraints as a murderer.

Q: Can a policyholder become a living donor by donating an organ or portion thereof and have a benefit payment made?

A: No. The donor must be deceased.

Q: Does Project Donor discriminate against those who cannot be donors?

A: No, this is not discrimination. There are untold examples of restrictions or ineligibilities placed intentionally or unintentionally on people's lives. If one is not old enough to receive Medicare benefits, it is not age discrimination. Unfortunately, not everyone is eligible for every government program. Medical unsuitability for organ donation is not discrimination.

Q: Will some beneficiaries sue for recovery because they have relied on the insurance proceeds, when in fact the benefits are payable only upon the successful recovery and transplantation of an organ and the deceased did not have an organ that was used?

A: No. The contract (and advertising of the program) clearly states the conditions for payment.

Q: Should the insurance policy mandate that the benefit be paid to the donor's estate?

A: No. That would constitute a third party choosing payment recipients, which amounts to coercion. This involves a gift from the donor, and the donor should select policy beneficiaries.

Q: Should the insurance policy mandate that the benefit be paid to a charity?

A: No. That will remove self-interest as an incentive, which will seriously harm Project Donor's effectiveness. Additionally, the donor has made a gift, and there is no reason why the government's gift to her/him should preclude them from choosing their own beneficiary, be it family, charity or other party.

Q: Would the payment of insurance benefits to the donor's beneficiary violate the law?

A: No. This is an insurance policy, not the buying and selling of organs. Nevertheless, appropriate addenda to the National Organ Transplant Act and the Uniform Anatomical Gift Act may be made as noted in the Project Donor Report to eliminate any ambiguity.

Q: Will administrative costs be greater than the \$250,000 described in the Project Donor Report?

A: They may well be, and a cost analysis should be done. Nevertheless, any additional amounts will be inconsequential both in absolute dollars and relative to the massive savings achieved by the plan.

Q: Should Project Donor be privatized, for reasons of efficiency, cost or distrust of government?

A: No! Project Donor is not a business or commercial venture! Society cannot allow profit-taking at the expense of suffering. The government function, beyond paying the benefits and insuring the huge savings are used for transplantation, is simply to register donors, maintain records and dispense death benefits as it already does with many programs, including Social Security and the Veterans Administration.

Q: Are there not increases in the organ recovery efficiencies of hospitals and organ procurement organizations which when made will increase the supply of organs and solve the problem?

A: No. While evidently there are steps needed to be taken in the request and recovery portion of the transplantation process, the *first* and most important goal is to convince donors to donate *before* they die, thus becoming potential donors. Having people decide to donate their own organs is absolutely foremost.

Q: Will Project Donor work?

A: Yes. There have been surveys done and reports written that seriously suggest the viability of a financial incentive to solve the organ donation shortage. Project Donor's life insurance concept is the most creative idea for a solution society has seen. The transplant community acknowledges that our previous efforts have not succeeded in preventing the deaths of people who are not transplanted in time. Now ten people die every day waiting for an organ. Project Donor must be implemented.

Q: Should a pilot study be done first?

A: No. Logistical problems such as lack of cohesive national advertising, locality idiosyncracies, administrative inefficiencies, local benefit payments under the aegis of the national United Network for Organ Sharing (UNOS) system, etc., would nullify the test's value as a prognosticator of national success. Project Donor implemented for all Americans is far more efficient, an act of fiscal responsibility and a program which can be effectively evaluated. Surveys have shown a financial incentive is worth pursuing. The test must be implemented as the national Project Donor United States Government Organ Transplant Life Insurance Policy.

April 15, 1999

PROJECT DONOR

**United States Government Organ Transplant
Life Insurance Policy**

The Solution to the Organ Donation Shortage

Project Developers

Eugene C. Epstein

**Alan W. Boessmann, D.V.M.
Liver Transplant Recipient
December 23, 1995**

Report Prepared and Written by

Alan W. Boessmann, D.V.M.

June, 1998

© Alan W. Boessmann, D.V.M.

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I. Executive Summary

It is a well-known fact that organ transplantation technology has progressed to a valid medical therapy, not only saving lives but restoring the afflicted to productive activity. It is also a well-known fact that there are currently not enough organs available to meet the need, largely due to the unwillingness of people and their families to agree to donate organs, either before or after death. Thousands of people die each year due to this shortage and the deficiency would be ameliorated and probably eliminated if all potential organ donors would indeed donate. Americans overwhelmingly endorse the concept of organ transplantation, but ironically do not fully support the concept by donating. Additionally, the reasons for refusal are not deeply held. Regardless of research efforts to mitigate the shortage, such as split-graft transplants and in-vitro growth of whole organs, a sure answer is to simply increase the number of organs donated, thereby applying the proven, most efficacious technology already in use. Overcoming the barriers to donation is the way to meet the need. An easy, simple, cost-effective method to obtain the requisite donations is a life insurance policy furnished by the United States government, benefits to be payable upon the donation *and transplantation* of the deceased's organs. Utilizing a common and popular financial instrument to convince the public to voluntarily participate in a program with which they already agree, we will solve the organ donation shortage.

II. The Problem

1. Explanation

People die of organ failure caused by various diseases. Allogenic whole organ transplantation (between individuals within the same species, such as human to human) is now a routine medical procedure that saves the lives of many of these people. Alternative transplant therapies are at this time either of limited or no use. Split grafts (transplanting a portion of a donor organ) using liver or pancreatic tissue are used in only selected situations. Growing replacement organs in the laboratory is under development, but its viability will only be realized in the distant future. Xenotransplantation (organs shared between non-human animals and humans) has not worked and is fraught with inherent medical difficulties including the spectre of panepidemics due to known, unknown and/or mutated animal viruses being transmitted to the human recipients with subsequent exposure to others with whom they are in contact.

The transplanting of organs from human to human is a proven life-saving procedure, which has already saved thousands of lives and will continue to do so in the future. Although there are issues to be resolved concerning the logistics of organ procurement, the basic problem is that there are not nearly enough organs donated to meet the need.

2. Statistics

These exhibits appear on the following pages:

- A. Number of U.S. Transplants - historical.
- B. Waiting List - historical.
- C. Reported Deaths on the Organ Procurement Transplant Network (OPTN) Waiting List - historical.
- D. Waiting List - current.
- E. Number of U.S. Organ Donors - historical.
- F. Number of Organs Retrieved Per Donor.
- G. Estimated Annual Number of Potential Donors.

Newsroom: Critical Data: Transplants
[Return to transplants table of contents](#)

Transplants

Exhibit A

Number of U.S. Transplants from 1988 to May, 1997 by Organ and Donor Type*

Organ	Donor Type	Year									
		1988	1989	1990	1991	1992	1993	1994	1995	1996	1997
Kidney*	Cad.	7231	7087	7783	7731	7697	8170	8383	8598	8559	3529
	Living	1812	1903	2094	2393	2534	2850	3007	3287	3486	1376
	Total	9043	8990	9877	10124	10231	11020	11390	11885	12045	4905
Liver	Cad.	1713	2199	2676	2931	3031	3404	3593	3878	4012	1668
	Living	0	2	14	22	33	36	60	44	50	20
	Total	1713	2201	2690	2953	3064	3440	3653	3922	4062	1688
Pancreas*	Cad.	244	413	526	530	554	772	840	1021	1011	414
	Living	5	4	2	1	3	2	2	6	10	5
	Total	249	417	528	531	557	774	842	1027	1021	419
Heart	Cad.	1669	1696	2096	2121	2170	2295	2338	2360	2342	949
	Living**	7	9	12	4	1	2	3	0	1	0
	Total	1676	1705	2108	2125	2171	2297	2341	2360	2343	949
Lung	Cad.	33	93	202	401	535	660	708	848	796	349
	Living	0	0	1	4	0	7	15	23	9	2
	Total	33	93	203	405	535	667	723	871	805	351
Heart-Lung	Cad.	74	67	52	51	48	60	70	70	39	21
	Living	0	0	0	0	0	0	0	0	0	0
	Total	74	67	52	51	48	60	70	70	39	21
Intestine+	Cad.			5	12	22	34	23	44	43	26
	Living			0	0	0	0	0	1	2	1
	Total			5	12	22	34	23	45	45	27
Total*	Cad.	10964	11555	13340	13777	14057	15395	15955	16819	16802	6956
	Living	1824	1918	2123	2424	2571	2897	3087	3361	3558	1404
	Total	12788	13473	15463	16201	16628	18292	19042	20180	20360	8360

Based on UNOS Scientific Registry data as of September 20, 1997

* In this table, Simultaneous Kidney-Pancreas transplants are counted twice, both in Kidney Transplants and in Pancreas Transplants. The number of Simultaneous Kidney Pancreas transplants performed in each year were: 1988-170, 1989-334, 1990-459, 1991-452, 1992-593, 1993-661, 1994-747, 1995-917, 1996-850

** Living heart donors donate their healthy heart when they become heart-lung recipients. This is called a "domino" transplant

Newsroom: Critical Data; Transplants

- + Data on Intestine transplants was not collected prior to April, 1994. At that time, information was collected retrospectively for transplants performed January, 1990-March, 1994.

Note: Double kidney, double lung, and heart-lung transplants are counted as one transplant. All other multi-organ transplants are being included in the total for each individual organ transplanted.

Data subject to change based on future data submission or correction.

Newsroom: Critical Data: Waiting List

Waiting List

Exhibits B and C

The size of the Organ Procurement Transplantation Network (OPTN) Waiting List at End of Year 1988 through 1996 by Organ

Organ	1988	1989	1990	1991	1992	1993	1994	1995	1996
Overall	13943	16294	17883	19352	22376	24973	27498	31045	34550
Heart	616	827	1237	1676	2323	2997	4059	5691	7467
Lung	2963	320	473	600	126	183	222	285	323
Kidney	0	0	0	0	778	923	1067	1234	1463
Liver	1030	1320	1788	2267	2690	2834	2933	3468	3698
Small Intestine	205	240	225	154	180	202	205	208	237
Pancreas	69	94	308	670	942	1240	1625	1923	2309
Total	16026	19095	21914	24719	29415	33352	37609	43854	50047

Data based on snapshot of the UNOS OPTN waiting lists on the last day of each year.

Reported Deaths on the OPTN Waiting List from 1988 through 1996

Organ	1988	1989	1990	1991	1992	1993	1994	1995	1996
Overall	739	750	917	975	1052	1285	1361	1510	1814
Kidney	0	0	0	0	15	61	71	86	91
Pancreas	6	23	21	37	33	3	13	4	5
Liver	195	284	316	435	495	562	657	799	954
Heart/Lung	494	518	612	779	780	763	724	769	746
Small Intestine	61	77	68	45	44	51	48	28	48
Lung	16	38	50	139	219	252	286	340	385
Intestine	0	0	0	0	0	3	15	19	22
Total	1502	1666	1962	2360	2580	2902	3055	3421	3916

Based on UNOS OPTN waiting list and removal files as of January 13, 1997. Data subject to change based on future data submission or correction.



Newsroom: Critical Data

Critical Data

Exhibit D

Weekly Facts about Transplantation for April 15, 1998

This page contains the most frequently requested statistics regarding transplantation and donation, including: numbers of patients on the waiting list, number of transplants performed in 1996, number of donors in 1996 and UNOS membership data. For more detailed data, use the buttons at left or go to the [Data](#) section above. If you can't find what you're looking for, you can submit your [data request](#) via the Internet.

The UNOS national patient waiting list for organ transplants contains over 58,000 registrations.

National patient waiting list	
39,086	registrations for a kidney transplant.
10,274	registrations for a liver transplant.
373	registrations for a pancreas transplant.
91	registrations for a pancreas islet cell transplant.
1,673	registrations for a kidney-pancreas transplant.
96	registrations for an intestinal transplant.
4,048	registrations for a heart transplant.
235	registrations for a heart-lung transplant.
2,797	registrations for a lung transplant.
58,673	TOTAL

NOTE: UNOS policies allow patients to be listed with more than one transplant center (multiple listing), and thus the number of registrations may be greater than the actual number of patients. As of April 15, 1998, there were 55,215 patients waiting for a transplant in the U.S.

Newsroom: Critical Data: Donors

Donors

Exhibit E

The following list of tables shows organ donor information based on data collected from the UNOS Organ Procurement Transplantation Network (OPTN) as of September 20, 1997. Data subject to change based on future data submission or correction.

[Donors by Organ and Donor Type](#)

[Donors by Race](#)

[Donors by Gender](#)

Number of U.S. Organ Donors by Organ and Donor Type from 1988 through May 31, 1997 by Year Donor Recovered

Organ	Donor Type	Year Donor Recovered									
		1988	1989	1990	1991	1992	1993	1994	1995	1996	1997
Kidney	Cadaveric	3,880	3,817	4,308	4,269	4,277	4,609	4,798	4,997	5,036	2,058
	Living	1,812	1,902	2,095	2,393	2,533	2,851	3,008	3,289	3,489	1,363
	Total	5,692	5,719	6,403	6,662	6,810	7,460	7,806	8,286	8,525	3,421
Liver	Cadaveric	1,835	2,377	2,871	3,167	3,335	3,764	4,095	4,324	4,451	1,855
	Living	0	2	14	22	33	36	60	45	52	20
	Total	1,835	2,379	2,885	3,189	3,368	3,800	4,155	4,369	4,503	1,875
Pancreas	Cadaveric	577	799	951	1,066	1,004	1,243	1,360	1,286	1,233	480
	Living	5	4	2	1	3	2	2	7	12	6
	Total	582	803	953	1,067	1,007	1,245	1,362	1,293	1,245	486
Heart**	Cadaveric	1,785	1,782	2,168	2,198	2,247	2,442	2,526	2,501	2,392	995
	Living	8	8	12	4	1	2	3	0	1	0
	Total	1,793	1,790	2,180	2,202	2,248	2,444	2,529	2,501	2,393	995
Lung	Cadaveric	130	191	275	395	527	790	918	908	750	322
	Living	0	0	1	4	0	12	31	41	12	3
	Total	130	191	276	399	527	802	949	949	762	325
Total	Cadaveric	4,084	4,019	4,512	4,528	4,521	4,861	5,100	5,357	5,416	2,241
	Living	1,825	1,916	2,124	2,424	2,570	2,903	3,102	3,375	3,553	1,386
	Total	5,909	5,935	6,636	6,952	7,091	7,764	8,202	8,732	8,969	3,627

** Living heart donors donate their healthy heart when they become heart-lung recipients. This is called a "domino" transplant



F. Number of Organs Retrieved Per Donor

3.5^{1, 2, 3}

¹“Through organ recovery improvements, the average number of transplants performed from each deceased donor has increased from 2.7 in 1988 to 3.5 in 1996.” U.S. Department of Health and Human Services, “Organ Transplantation: A Success Story,” *National Organ and Tissue Donation Initiative*, Washington, D.C.

²April, 1998, teleconferences with Ms. Carol L. Beasley, MPPM, Managing Director of the Partnership for Organ Donation, Boston, Massachusetts, and Ms. Gwen Mayes, Chief, Operations and Analysis Branch, U.S. Department of Health and Human Services, Division of Transplantation.

³Patrick McNamara and Carol Beasley, “Determinants of Familial Consent to Organ Donation in the Hospital Setting,” *Clinical Transplants 1997*, Cecka and Terasaki, Eds., Los Angeles, California: UCLA Tissue Typing Laboratory.

G. Estimated Annual Number of Potential Donors

13,000

13,000-15,000¹12,500²10,000-14,000³12,000-15,100³

¹The number above refers to cadaveric donors. Living donors (essentially only kidneys), potentially numbering 10,000, would add significantly to the donor pool. April, 1998, teleconferences with Ms. Carol L. Beasley, MPPM, Managing Director of The Partnership for Organ Donation, Boston, Massachusetts.

²April, 1998, teleconference with Howard M. Nathan, Executive Director, Delaware Valley Transplant Program, Philadelphia, Pennsylvania.

³Patrick McNamara and Carol Beasley, "Determinants of Familial Consent to Organ Donation in the Hospital Setting," *Clinical Transplants 1997*, Cecka and Terasaki, Eds., Los Angeles, California: UCLA Tissue Typing Laboratory.

Conclusions:

- The number of organ transplants performed is steadily increasing each year (55 per day in 1996).¹
- The number of people on the waiting list for organs is dramatically increasing each year (by 212% from 1988 to 1996).²
- The number of organ donors is increasing each year but at a very slow rate.³
- Approximately 10 people die every day while waiting for an organ.⁴
- If all potential donors would donate, *in theory* it would take only 14-1/2 months to acquire the number of organs necessary to transplant the 55,215 people on the April 15, 1998, UNOS national patient waiting list: retrieving an average of 3.5 organs per donor would necessitate 15,776 donors to provide transplants for these people ($55,215 \div 3.5$) and based on a potential annual cadaveric donor pool of 13,000, the organs would be acquired in 14-1/2 months as stated ($15,776 \div 13,000 \times 12$).
- If all potential donors would donate and the patients currently on the waiting list were all transplanted, the only remaining patients waiting for an organ would be the annual new listees. Approximately 33,768 people were added to the waiting list in 1996⁵, requiring 9,648 donors to enable their transplantation ($33,768 \div 3.5$). *In theory*, it would take only 9 months and 74 percent of the potential annual cadaveric donor pool to transplant the newly listed organ transplant candidates ($9,648 \div 13,000$).
- Obviously, the calculated figures and timetables above are theoretical projections only and are based on numbers which are snapshots of an ever-changing, dynamic situation. Realization of the actual numbers, time frames, specific organ matchings, donor-recipient matchings, increases in living donors, and additions to the waiting list all impact on the outcomes attained. Use and/or expansion of transplant community resources is also crucial to the success of transplanting additional patients. *Nonetheless, these figures are significant and of statistical inference.* They show that

¹U.S. Department of Health and Human Services, "Organ and Tissue Donation and Transplantation," *National Organ and Tissue Donation Initiative*, Washington, D.C.

²"Organ and Tissue Donation and Transplantation," *op. cit.*

³Steven L. Gortmaker, Ph.D., et al., "Organ donor potential and performance: Size and nature of the organ donor shortfall," *Critical Care Medicine*, 1996. Vol. 24, No. 3, p. 432.

⁴Gortmaker, "Organ donor potential and performance," *op. cit.*

⁵This figure is somewhat high due to double listings. United Network for Organ Sharing (UNOS), 1997 Annual Report, Table 6, p. 234.

if all potential donors donate and if the medical community gears up to handle the influx of transplant procedures now made possible, we can *solve* the organ donation shortage (the availability of organs "off the shelf" would promote additional patient wait-listings as a result of physicians being increasingly amenable to prescribing transplantation as a treatment modality, but eventually these referrals would plateau according to the dictates of sound medical practice). At the very least, if there is a significant increase in donation we can save the lives of the ten people who die each day waiting.

3. Transplantation and Donation: An American Dichotomy

Overwhelmingly, Americans endorse the concept of organ transplantation:⁶

- “Nearly nine in ten Americans support the general concept of organ donation.”
- “Virtually all respondents agree that organ donation allows something positive to come from a person’s death.”
- “Nearly four in five Americans would accept a needed organ transplant. Nearly half (46%) of respondents who initially indicated opposition to organ donation indicate they would accept one if necessary.”
- “The majority of Americans believe their families support the idea of organ donation.”
- “. . . if a family member requests their organs be donated, nearly all respondents (93%) would be likely to honor that wish.”
- “Most Americans (85%) believe organ transplants extend the recipient’s life and that the additional years are healthy ones.”
- “More than two-thirds of Americans believe that most people who need transplants do not receive them.”

Ironically, Americans do not overwhelmingly support the concept *by donating*:⁷

- “Both studies found that family refusal to donate was the principal reason for non-donation. In the Seminoff study, 54% of families declined organ donation when it was offered; in the Gortmaker study (4), the corresponding figure was 52%.”⁸
- “More than one-third of Americans (37%) reported they are very likely to donate their own organs after their death and an additional one-third (32%) reported they are somewhat likely to donate. One-quarter (25%) are not likely to donate their organs.”⁹

⁶The Gallup Organization, Inc., “The American Public’s Attitudes Toward Organ Donation and Transplantation,” conducted for The Partnership for Organ Donation, Boston, Massachusetts: February 1993.

⁷Gallup Organization, “The American Public’s Attitudes,” op. cit.

⁸Patrick McNamara and Carol Beasley, “Determinants of Familial Consent to Organ Donation in the Hospital Setting,” *Clinical Transplants 1997*, (Chapter 21) Cecka and Terasaki, Eds., Los Angeles, California: UCLA Tissue Typing Laboratory.

⁹Gallup Organization, “The American Public’s Attitudes,” op. cit.

- “Although a high percentage of Americans (85%) approve of organ donation, less than half (42%) have themselves made a personal decision about donation of their own organs. Even fewer (25%) have made a decision about the donation of family members’ organs.”
- “More than half of Americans (55%) either have or are willing to formally grant permission for the donation of their organs. However, only slightly more than one-quarter (28%) have already done so.”
- “Although more than half of respondents likely to donate their organs have expressed their feelings to family members, a nearly equal proportion have not done so.”
- “The results of Table 18 further reflect a substantial lack of critical family discussion with less than one in three respondents indicating that family members have expressed whether or not they wish to have their organs donated after death.”

Interestingly, American reasons for not donating are generally vague and tenuous:¹⁰

- “Nearly half of respondents currently unwilling to donate their organs may be amenable to persuasive information since 47% were unable to give a concrete reason for their current stand.”
- “Religious barriers to organ donation do not appear to be widespread.”
- “The small proportion of Americans who believe they are too old to donate their organs was primarily found among those aged 55 and older.”
- “Nearly nine in ten Americans believe doctors use all their resources to save a person before deciding to pursue organ retrieval.”
- “Nearly two-thirds of Americans recognize that a brain dead person cannot recover from his or her injuries.”
- “Although the majority of respondents recognize that donor families are not required to pay extra medical bills associated with the donation, there is a substantial amount of uncertainty surrounding this issue.”
- “More than four in five Americans believe that it is possible to have a ‘regular’ funeral service for an organ donor.”

¹⁰Gallup Organization, “The American Public’s Attitudes,” op. cit.

- 78% of respondents agree that it is not important for a person's body to have all of its parts when it is buried.
- "There is some concern about disfigurement associated with organ retrieval, although the majority of respondents indicate they are not concerned about this aspect of organ donation."
- "More than half of Americans (58%) disagree that a poor person has as good a chance as a rich person of receiving an organ."

The most important reason why people do not make provisions to be organ donors seems to be a reluctance or unwillingness to think about, acknowledge and deal with our own mortality:¹¹

- "More than one-third of Americans admit to some level of discomfort surrounding thoughts of their own death."
- "Respondents who are likely to donate their organs after death but who are unwilling to discuss this wish with their family indicate a general reluctance to discuss issues surrounding death."

Conclusion:

Americans appreciate the value of organ transplantation and approve its use as a medical therapy. Nevertheless, there is a low rate of organ donation for reasons which are not convincing or deeply held. Recognizing and preparing for death, a requirement for signing donor cards, is ripe territory for benign neglect.

An appropriate compensating benefit often serves to overcome reluctance to act when confronted with distasteful situations.

¹¹ Lloyd R. Cohen, "Increasing the Supply of Transplant Organs: The Virtues of an Option Market," 1995.

III. The Solution

1. United States Government Organ Transplant Life Insurance Policy

A no-cost organ transplant life insurance policy in the amount of \$10,000.00 is issued by the United States government or Congressionally chartered non-profit organization, the benefit payable to a directed beneficiary, upon the transplant of any one or more major organs from a deceased individual. The donor card and/or life insurance contract are revocable by the donor. The names of the beneficiary(s) are strictly confidential, inaccessible to family members, medical personnel and others. The donor card and insurance contract are binding and enforceable in a court of law. No member of the donor's family has the right or power to void the agreement, pursuant to the Uniform Anatomical Gift Act (1987), Section 2.(h).

2. Rationale for Success

Simply put, the \$10,000.00 insurance benefit will serve to overcome people's reluctance to sign donor cards. The reasons for not signing donor cards are for the most part indistinct and indefinite; and including donor beneficiaries as financial beneficiaries in the transplantation process, as we do with doctors, hospitals, transplant organizations and health insurance companies, will increase organ donation to meet the need. Organs will be readily available, thousands of lives will be saved, recipients will in many cases return to productive society and families will regain their future.

Instituting and recording a voluntary, no-cost enforceable insurance contract, with the accompanying signed donor card, will additionally succeed in:

- eliminating painful decisions by the grieving family of a deceased because the deceased will have clearly indicated his or her desire to donate and the formal recording of legal documents will empower Section 2.(h) of the Uniform Anatomical Gift Act.
- eliminating painful donor requests by doctors and administrators of the deceased's family.
- eliminating hospital concerns over lawsuits by establishing a contractual basis for the expeditious acquisition of organs.
- establishing a national donor registry for use in carrying out donors' wishes.

3. Financials

It is axiomatic that cost analyses concerning organ transplantation involve estimation and extrapolation. In the case of Project Donor, the results are dramatic.

Expenditures

a) The cost to the United States government for insurance benefit payments to provide transplants for the patients currently on the waiting list is estimated at \$157,760,000.00. This figure is arrived at by the following calculation:

No. of donors needed to satisfy current need x \$10,000.00 per donor = total insurance benefit payments

$$15,776 \times \$10,000.00 = \$157,760,000.00.$$

(See II.2. Conclusions)

This amount would be paid out over time as transplant procedures are completed.

b) The insurance benefit payments to provide transplants annually are estimated at \$96,480,000.00. This figure is arrived at by the following calculation:

No. of donors needed to satisfy annual need x \$10,000.00 per donor = annual insurance benefit payments.

$$9,648 \times \$10,000.00 = \$96,480,000.00$$

(See II.2. Conclusions)

c) Administrative costs are estimated at \$250,000.00 per year. This figure is somewhat arbitrary but the following parameters were applicable to its estimation:

- The agency administering the policy must be at least minimally staffed twenty-four hours per day, every day, in order to both process policy contracts and assist with the policy verification requests by Organ Procurement Coordinators which will occur at all hours (see III. 4. Administration).
- Third- party administrators in the medical insurance industry process health claims. The standard cost allocated per claim is \$4.00-\$5.00 which includes a profit margin.¹²

¹²Kevin Sampson, Health Benefits Associates, Reno, Nevada.

Administration of the organ transplant life insurance policy will be on a non-profit basis. Nevertheless, as an example, applying a \$5.00 cost factor per transaction to 50,000 annual "policy transactions" results in an annual administrative cost of \$250,000.00.

Savings

Successful implementation of Project Donor, resulting in the availability of organs "off the shelf," will accrue savings in health care costs which will no longer be incurred to keep people alive while waiting for transplant. These costs are enormous. Except for kidney disease patients, where costs are handled by Medicare and thus more readily calculated, the money spent in maintaining the various transplant candidates is difficult to ascertain because of large variables in the number of health providers, in and out patient care, differing definitions of costs, etc., etc.

Richard H. Hauboldt, F.S.A., of Milliman & Robertson, Inc., an international actuarial firm, states: "Candidacy costs include the costs of maintaining the patient while awaiting transplantation" and has assigned a cost of \$10,600.00 per month to maintain heart, liver, heart-lung and lung transplant candidates.¹²

The annual health care costs incurred to keep these patients currently on the waiting list alive while waiting for an organ is thus estimated at \$2,207,428,800.00. This figure is arrived at by the following calculation:

No. of above patients as of April 15, 1998, x \$10,600.00 x 12 = annual candidacy costs

$$17,354 \times 10,600.00 \times 12 = \$2,207,428,800.00$$

As can be readily seen by these figures, the difference between the insurance benefit payments and the candidacy costs show a huge net savings by Project Donor, the proceeds of which should be directly applied to the organ transplant procedures, by the recipients of the savings (insurance companies, Medicare, Medicaid). It makes economic sense and the health insurance industry, considering its current coverage of and projected expansion in paying transplant related costs (Exhibit B), should be mandated to participate *fully* in covering organ transplantation expenses.

Specifically concerning kidney disease patients, Paul W. Eggers, Ph.D., wrote:

¹²Richard H. Hauboldt, F.S.A., *Research Report: Cost Implications of Human Organ and Tissue Transplantations*, Milliman & Robertson, Inc., Brookfield, WI: pp. 28-30.

"Patient registration and monitoring while awaiting transplant can add significant costs to transplantation. In fact, the office of the Inspector General in the Department of Health and Human Services found that waiting list costs were one of the major costs associated with kidney transplantation."¹³

"The results of this study confirm the widely held belief that kidney transplantation is, over time, a less costly alternative to maintenance dialysis. The high initial cost of transplantation is recovered in about 4-1/2 years with a net discounted savings of about \$42,000 over a 10 year time frame."¹⁴

"In terms of overall cost-effectiveness, kidney transplant has been shown to be consistently superior to dialysis, in terms of both Medicare expenditures and total estimated costs. Similar results have been found in other countries."¹⁵

His findings are particularly significant in that patients waiting for kidneys comprise two-thirds of the OPTN Waiting List.

Conclusion

Obviously the pro forma expenditures and savings presented are affected by such variables as cost estimations, the number of transplants performed over time, the numbers of patients added to waiting lists, etc. Nonetheless, these figures are significant and of statistical inference. **There is a huge projected net savings.**

The benefit payments are made from a fund established by Congress and contributed to by the health insurance industry in accordance with whatever statutory obligations are instituted to maximize the financial benefits of Project Donor in saving lives through transplantation.

¹³Paul W. Eggers, Ph.D., and Lawrence E. Kucken, M.P.A., "Cost Issues in Transplantation," *Surgical Clinics of North America*, Vol. 74, No. 4, October 1994, p. 1259.

¹⁴Paul Eggers, Ph.D., "Comparison of Treatment Costs Between Dialysis and Transplantation," *Seminars in Nephrology*, Vol. 12, No. 3 (May), 1992, pp. 284-289.

¹⁵Eggers, "Cost Issues in Transplantation," p. 1264.

4. Administration

Publicizing availability of the life insurance policy is accomplished through existing and aggressive future venues, most notably the new National Organ and Tissue Donation Initiative recently launched by U.S. Department of Health and Human Services (HHS) Secretary Donna E. Shalala. The HHS "... announced new partnership efforts with more than a dozen private and volunteer organizations," including the Coalition on Donation, American Medical Association, American Hospital Association and American Bar Association. Appropriate terminology is simply added to educational messages promoting donation, advising the public of their option of receiving a no-cost life insurance policy. Insurance companies and health maintenance organizations could participate in marketing the policy. People sign donor cards and insurance contracts (both in duplicate) simultaneously. Cards and contracts can be requested from UNOS and are offered in tandem at the usual outlets.

The existing system for acquiring and allocating organs remains intact. Certain logistical additions are made to implement the policy:

1. an "insurance agency" is created and staffed by the federal government.
2. copies of signed donor cards and insurance contracts are forwarded to the agency, with the originals retained by the insured. A postcard receipt is returned by the Agency. Both documents may be revoked by the donor by contacting the agency in writing.
3. at death, verification of an insurance policy is completed by the Organ Procurement Coordinator handling the donation process by contacting the agency:
 - a) if the deceased has a policy, a copy of the contract is immediately faxed to the coordinator. By contract, the coordinator can now acquire the organs according to existing procedure.
 - b) if the deceased does not have a policy, decisions about organ donation are handled according to existing procedure.
4. Cadaver Donor Registration/Referral Forms are already submitted to UNOS by the Organ Procurement Organization. Upon receipt of a copy of the Form from UNOS, the insurance agency verifies existence of a policy and pays the benefit amount to the beneficiaries within thirty days or less.
5. The following new form is required:
 - a) life insurance policy contract (Exhibit A).
6. The Cadaver Donor Registration/Referral Form must be amended to include the following information:
 - a) was an insurance policy contract effectuated by the deceased?

IV. Legislation

Changes in law will be required. At the least, the following Acts must be addressed to include the United States Government Organ Transplant Life Insurance Policy.

Uniform Anatomical Gift Act (1987)

- Section 1. define life insurance policy
- Section 2. amend to include specifics of policy
- Section 3. amend to include specifics of policy
- Section 5. amend to include specifics of policy
- Section 7. amend to include specifics of policy
- Section 10.(a) amend as follows: "The United States Government Organ Transplant Life Insurance Policy is not an act of purchase or sale."

National Organ Transplant Act (1984)

Title III, Sec. 301.(a) amend as follows: "The United States Government Organ Transplant Life Insurance Policy is not a transfer of organs for valuable consideration."

V. Project Developers

1. Eugene C. Epstein
1238 Wrightstown Road
Newtown, PA 18940
2. Alan W. Boessmann, D.V.M. (liver transplant recipient, December 23, 1995)
15310 Pinion Road
Reno, NV 89511

For inquiries, contact Eugene E. Epstein at address above or fax at (215) 860-1862.

VI. Exhibits

- A. United States Government Organ Transplant Life Insurance Policy Contract.
- B. Letter from Richard H. Hauboldt, F.S.A., Milliman & Robertson, Inc., May 11, 1998, re: transplant coverage.

Exhibit A
United States Government Organ Transplant
Life Insurance Policy
Contract

23

I. Authorization of the Donor. The person named below (hereinafter to be referred to as "Donor") hereby authorizes and approves, upon Donor's death, an Organ Procurement Organization (OPO) operating within the Organ Procurement and Transplantation Network, as authorized by the National Organ Transplant Act of 1984, and in accordance with the OPO's customary procedures, to remove and recover for the purpose of transplantation, organs from the Donor's body as specified in the Donor's Organ Donor Card.

The rights granted and authorized herein are subject to no limitation or special provisions except those set forth on Donor's Organ Donor Card. Furthermore, the rights granted and authorized by this agreement shall be binding upon all agents, representatives, heirs, and attorneys-in-fact of the Donor.

II. Obligation of the Agency. In exchange for the authorization granted herein by the Donor, the Organ Transplant Life Insurance Agency (hereinafter to be referred to as Agency) shall:

A. Pay to the person(s) trust, business, charity or any other individual(s) or entity of the Donor's choosing, or in lieu of such choice to the Donor's estate, the sum of TEN THOUSAND DOLLARS (\$10,000) upon the successful recovery and transplantation of at least one of Donor's major organs (including but limited to the kidney, liver, heart, lung or pancreas).

B. Maintain the confidentiality of the Donor. The Agency may notify or inform an authorized hospital official or organ procurement officer of the existence of this contract and Donor's intention to be an organ donor. Provided further that in the event of the Donor's death, the Agency may notify the beneficiary named below of the nature and existence of the contract. The Agency is expressly prohibited from disclosing the nature and existence of the contract to any other individual, entity, or organization.

III. Termination Procedure. This contract may be terminated at any time without penalty: (1) by the Agency by written notification to the donor, and (2) by the donor by written notification to the Agency.

IV. Beneficiaries. The Donor elects the following person(s), trust, business, charity or any other individual(s) or entity to receive the insurance proceeds resulting from the fulfillment of the terms of this contract. Failure or inability to designate a recipient(s) will result in payment of the insurance proceeds to the estate of the Donor.

V. **Signature.** I have read, understood, and agree to all the terms of this document.

Donor

Name: _____
 Street Address: _____
 City/State/Zip: _____
 Social Security Number: _____
 Signature: _____
 Date: _____

Organ Transplant Life Insurance Agency

Address: _____ [Preprinted]
 Telephone Number: _____ [Preprinted]
 Name and Title of Authorized Agent: _____ [Preprinted]
 Signature: _____ [Preprinted]
 Date Received: _____

A postcard receipt will be sent to the donor by the Agency.

Exhibit B



MILLIMAN & ROBERTSON, INC.
 Actuaries & Consultants
Internationally WOODROW MILLIMAN

Suite 400, 15800 Bluemound Road, Brookfield, Wisconsin 53005-6069
 Telephone: 414/784-2250
 Fax: 414/784-4116

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May 11, 1998

Mr. Alan Boessmann, DVM
 15310 Pinion Road
 Reno, Nevada 89511

Re: Transplant Coverage

Dear Alan:

During our conversation last week regarding transplant costs and coverage, you asked that I summarize the population distribution by insurance market that we discussed. The distribution of insurance coverage by market can be used to approximate the number of transplants covered by government programs as compared to private markets. Naturally other methods could be used. In addition, included in this letter, are two transplant distributions which we did not discuss, that may provide a more accurate allocation than the population distribution. I understand that you may use this information in your meeting with Health and Human Services when you present your funding idea for certain transplant costs.

I have obtained some updated population estimates since we talked. In the following table, non-Medicare population estimates are from the Employee Benefit Research Institute for 1996. Medicaid numbers were adjusted to account for overlap of coverage. Medicare population is based on my judgment.

Health Insurance Market	Estimated 1996 Population (millions)	Percent
Private	166	62%
Uninsured	41	15%
Public (Medicare/Medicaid)	62	23%
Total	269	100%

Albany, Atlanta, Boston, Chicago, Dallas, Denver, Hartford, Houston, Indianapolis, Irvine, Los Angeles, Milwaukee, Minneapolis, New York, Omaha, Philadelphia, Phoenix, Portland, ME, Portland, OR, St. Louis, Salt Lake City, San Diego, San Francisco, Seattle, Tampa, Washington, D.C., Bermuda, Tokyo

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Mr. Alan Boessmann, DVM
 May 11, 1998
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Population distributions do not reflect that only about 3% of transplants are performed for people over age 65 and that, in the past, Medicare has covered most (I estimate about 90%) of kidney transplants under the End Stage Renal Disease program. The table below shows the expected distribution of transplants taking these two items into account. The total number of transplants is based on M&R research and includes heart, liver, kidney, kidney-pancreas, pancreas, heart-lung, lung and bone marrow. Allocations to non-Medicare markets assume a uniform incidence rate.

Health Insurance Market	Estimated 1998 Transplants, 90% of Kidney Covered by Medicare	Percent
Private	15,910	47%
Uninsured	3,930	12%
Public (Medicare/Medicaid)	13,861	41%
Total	33,701	100%

Recently the waiting period during which an employer plan is primary versus Medicare for kidney transplants under the End Stage Renal Disease program has changed from 18 months to 30 months. I believe that this change could result in only 10% of kidney transplants being covered by Medicare. The impact of the waiting period change will take some time to be realized. As an illustrative example only, the distribution of transplants by insurance market with this assumption is shown below.

Health Insurance Market	Estimated 1998 Transplants, 10% of Kidney Covered by Medicare	Percent
Private	25,523	75%
Uninsured	3,930	12%
Public (Medicare/Medicaid)	4,248	13%
Total	33,701	100%

Mr. Alan Boessmann, DVM
May 11, 1998
Page 3

The actual transplants by market will vary from the values in this letter. The transplant incidence rate within the non-Medicare markets may not be uniform, especially for Medicaid. This letter should be shared with others only in its entirety. The reader is assumed to be familiar with the different ways of financing health care, both public and private.

If you would like to discuss the values in this letter further, please feel free to call me at 414/784-2250.

Sincerely,

A handwritten signature in cursive script, reading "Richard Hauboldt".

Richard H. Hauboldt, F.S.A.
Consulting Actuary

RHH/mm

